1999

Optimization of Insertion Holes and Anchor Design for Cylinder Shaped Toggle Type Suture Anchors

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Optimization of Insertion Holes and Anchor Design

for Cylinder Shaped Toggle Type Suture Anchors

(TITLE)

BY

Adam Fedenia

THESIS

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF

Master of Science in Technology

IN THE GRADUATE SCHOOL, EASTERN ILLINOIS UNIVERSITY
CHARLESTON, ILLINOIS

1999

YEAR

I HEREBY RECOMMEND THIS THESIS BE ACCEPTED AS FULFILLING
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Abstract

This research was performed to optimize insertion holes and anchor design for cylinder shaped toggle type suture anchors. Four types of anchors were investigated in terms of pull strength and design in acrylic plate and pig bone. They included small type A and B anchors and large type A and B anchors.

Pull strength trends suggest that the small type anchors behave similarly since their external dimensions are identical, with the exception of type A anchor having a hole running from one end of the cylinder to the other like a pipe. It was found that the suture would fail primarily at the anchor for both small anchors. SEM analysis provided a clear image of what was occurring to the suture/anchor in tension. The 0.889 mm suture hole in the anchor did not allow enough clearance for the USP #2 suture under applied load. As a result, the anchor design limits the anchor from achieving a maximum strength.

Based upon the observations on implementation, an insertion hole diameter between 2.3 and 2.4 mm would be desirable for the small anchors. Nonetheless, the 2.4 mm hole diameter was close to the 2.5 mm hole in which all tests failed upon toggle. It was recommended that a hole size of 2.3 mm be used because of easy implementation, consistently high pull strengths and relatively low standard deviations in pull strength testing.

Large anchor type A and B showed a different pull strength trend. Large anchor A demonstrated characteristics similar to the smaller anchors. The suture/anchor system failed due to suture fracture near the hole of the anchor. It was noticed that the small type anchors and large type A anchor had the same suture hole diameters of 0.889 mm, which limited the suture to reach its potential strength.

Large anchor type B failed predominantly at the knot. It demonstrated a pull strength and standard deviation closer to that of USP #2 suture. The suture hole diameter of 1.17 mm shifted the failure point away from the anchor to the knot. Given the observations on implementation and pull strength, it was recommended that an insertion hole of 3.3 mm be used because of its impressive pull strength and relatively low standard deviation.

Dedication

I would like to take this opportunity to express sincere gratitude to my family and friends for their understanding and encouragement. I would especially like to express my heartfelt appreciation to my future wife Keri, for her devoted attention and patience throughout this research. Without their support, this research would not have been possible.

Acknowledgment

I would like to give my deepest admiration and respect to Dr. Ping Liu for his dedication and guidance through the research and writing process. I would like to thank Dr. Clifford Strandberg and Dr. Louis Butler for taking time and serving as honorable members of my thesis committee. I would also like to thank Bonutti Research, Effingham, IL, and the School of Technology, Eastern Illinois University, Charleston, IL, for supporting my research entirely.

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CHAPTER 1

Introduction

A human shoulder is home to an arrangement of bones, muscle, ligaments, and tendons. The shoulder joint allows shoulder and arm rotation for movement in practically any direction within reason (National Institute of Arthritis and Musculoskeletal and Skin Diseases [NIAMS], 1997). Unfortunately, the shoulder is also a site of numerous injuries. It is estimated that each year four million people in the U.S. seek medical care for shoulder sprain, strain, dislocation, rotator cuff tear, or other problems. About one and a half million of those people will need surgery (NIAMS, 1997).

Suture anchors were developed to assist in the reattachment and healing process for severe torn rotator cuffs. They simplify the fixation of soft tissue to bone, while their small size enables them to be completely buried into the bone (Carpenter, Fish, Goldstein, & Huston, 1993). The main consideration in designing an anchor is that the anchor should securely fasten to the bone so healing is achieved safely and effectively.

This study focused on toggle type anchors of cylinder shape. The anchor has two suture holes running perpendicularly through its axis. The anchor is designed to be inserted along its length into the bone through a predrilled insertion hole, with the rear end of the anchor acting as a pivot point inside the bone. After insertion and the suture being toggled by the surgeon, the pivot point catches bone material and causes the anchor to maneuver ninety degrees or to lay parallel to the surface of the bone. The locking security or pull strength of this anchor is related to bone quality, bone thickness, insertion hole dimension, anchor design, and its application procedure.

1.1 Statement of the Research

The purpose of this research was to determine the effect of insertion hole diameters and anchor design on the pull strength of cylinder shaped toggle type suture anchors.

1.2 Significance of the Research

The results obtained through this research provide a fundamental understanding of toggle type anchors. An in depth investigation on insertion hole size and anchor design of cylinder shaped toggle type anchors helps improve the pull strength of suture anchors. Thus, the security and reliability of the anchor can be enhanced.

1.3 Assumptions

The cylinder shaped toggle type suture anchors for this study are designed to be inserted length ways into the bone with one end of the anchor acting as a pivot point. This pivot point causes the anchor to maneuver ninety degrees or to lay parallel to the surface of the bone after being toggled.

The sutures used for testing are identical.

There is minimum variation among suture anchors for each design.

The acrylic plates used as a testing model material are uniform in terms of their mechanical properties.

Fresh pig bones used in this research are uniform in testing areas.

1.4 Limitations

The following conditions may influence the pull strength of a cylinder shaped toggle type suture anchor:

Contaminants in anchors such as burrs could promote suture laceration.

Water absorption in the suture.

Variation in suture strands.

The quality and thickness of the model material.

Testing errors associated with the testing equipment and the operator.

1.5 Delimitations

The following parameters were controlled in this study:

This research focused on cylinder shaped toggle type suture anchors. The suture anchors used in this study were made of 316L stainless steel or titanium alloy. Each test used a different anchor and suture. The anchors were inserted into each sample using an insertion device.

The suture type used in the study was: USP #2; SP257, polyviolene, green braided, coated, nonabsorbable, non-sterile surgical suture, with a diameter ranging from 0.5 to 0.59 mm.

The first testing model was acrylic plate. The other testing model for this study involved fresh pig shoulder bones. The metaphyseal cortex region was tested. For each hole being drilled; two passes, down and then up with the drill bit were required for both the acrylic plate and bone models.

Eight tests were performed on acrylic plates and five tests were conducted on fresh big bones. The reason for less tests on pig bones was that the bone surface area on one bone will not accommodate more than five tests for each hole size.

All tests were performed on the Instron 4467 universal testing machine (Instron Corp., Canton, MA) in the Materials Testing Lab at Eastern Illinois University.

Failure analysis was conducted utilizing a variable pressure scanning electron microscope (Hitachi 3500N) in the Scanning Electron Microscopy Lab at Eastern Illinois University.

1.6 Hypothesis

Changing the insertion hole diameter and modifying the design of the cylinder shaped toggle type suture anchor affect its pull strength.

1.7 Definitions

Anchor pullout: The anchor is pulled completely out of the bone without suture failure (Barber, Click, & Morley, 1995).

Bioabsorbable anchors: Suture anchors composed of material (e.g., polyglycolide [PGA] and poly L-lactic acid [PLLA]) that can be broken down by the body over time (Adriano & Pohjonen, 1994; Barber & Deck, 1995; Barber, Cawley, & Prudich, 1993; Barber, Click, & Morley, 1997; Middleton & Tipton, 1998) .

Cancellous bone: Spongy bone containing red marrow starting from the metaphyseal cortex and ending at the head of the humerus (Tortora, 1995).

Deadman theory: A theory which simulates the suture anchor system. The deadman or rock is similar to the suture anchor, whereas the deadman wire is symbolic of the suture, and the fence post represents the severed tendon (Burkhart, 1995).

Diaphyseal cortex: A region of thick bone (3 to 4 mm compact bone) that protects soft yellow marrow and makes up the bone shaft (Tortora, 1995).

Humerus bone: The humerus bone is the scientific name for the upper arm bone located between the elbow and shoulder.

Introduction device: A device used to introduce the anchor into the bone.

Insertion hole: The hole drilled in the bone in order to insert the anchor.

Ligament: Ligaments attach bones to each other (NIAMS, 1997).

Metaphyseal cortex: A bone region containing spongy (cancellous) bone, which is protected by 1 to 2 mm thick compact bone, and is located between the head of the humerus and the diaphyseal bone region (Tortora, 1995).

Mini-anchors: Anchors that have an insertion hole or minor diameters less than 2.2 mm (Barber, Click, et al., 1997).

Non-screw anchors: Anchors that do not resemble a screw or contain screw-like characteristics. Non-screw anchors either impact, deploy, or toggle upon insertion (Barber, 1997).

Pull strength: The amount of load it takes for the anchor to fail or the suture to break during testing.

Screw anchors: Anchors which resemble a screw or contain screw-like characteristics, such as threads (Barber, 1997).

Suture anchor: The suture anchor is a surgical device implanted inside of the human bone. The anchor acts as a securing mount for the suture, while the other end of the suture is tied around ruptured tendons and ligaments. The suture forms a bond, causing the separated tendon or ligament to progressively grow back onto the bone (Barber et al., 1993).

Suture discoloration: Suture changes color in an area where pinching occurred.

Suture fray: Some of the strands in the suture break during insertion, usually caused by pinching.

Tendon: Any cords of tough and fibrous tissue connecting muscles to bones or other parts (NIAMS, 1997).

Toggle type suture anchors: Non-screw anchors inserted into predrilled holes and then toggled by surgeons to securely fasten to bones.

Transosseous suture technique: The process of drilling bone tunnels into the shoulder and inserting the suture through the bone and tendon for the purpose of reattachment (Burkhart, 1997a).

CHAPTER 2

Literature Review

The first suture anchor was developed in 1985 (Craft, Cawley, Moseley, & Noble, 1996; Goble, Clark, Olsen, & Somers, 1994). Prior to 1985, surgeons had to use a number of primitive techniques to repair a torn rotator cuff. Figure 1 shows a diagram of the shoulder (Tortora, 1995). A torn rotator cuff consists of a tear in any one or all of the tendons and ligaments due to strenuous acts. Tendons attach the various muscles to the top part of the upper arm bone (head of the humerus), whereas ligaments attach bones to each other (Stone, 1996).

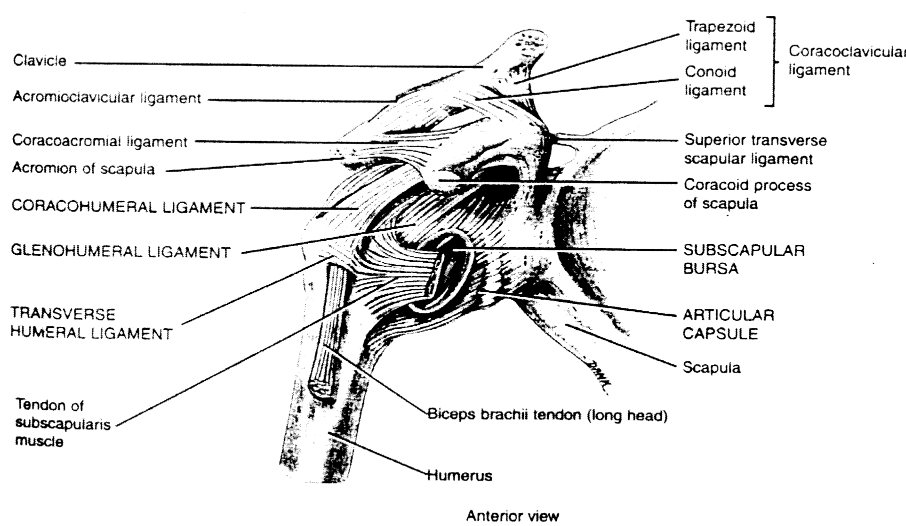

Figure 1. Diagram of the shoulder.

Figure 2 illustrates a transosseous suture technique to repair torn rotator cuffs (Craft et al., 1996). The surgery consists of drilling tunnels through the upper humerus region located at the shoulder so that the suture can loop through the bone and tendon (Burkhart, 1997a; Burkhart, Johnson, Wirth, & Athanasiou, 1997; Steinbeck & Jerosch, 1998). Tightening the loop causes the ruptured tendon to rest on the bone, beginning the healing process.

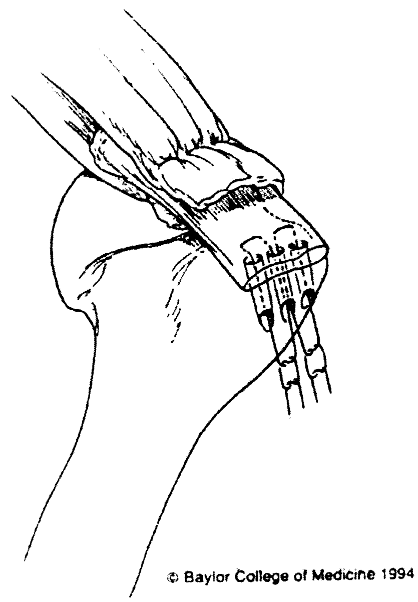

Figure 2. The transosseous suture tunnel repair.

However, the transosseous suture technique was not satisfactory for its purpose. The technique is time consuming, which requires large exposure of the bone, and only the most skilled surgeons could perform the surgery (Burkhart, 1997a; Carpenter et al., 1993; Shall & Cawley, 1994). A study by Burkhart (1997a) showed that after months of implantation, the surgical suture would cut through the bone like a wire slicing through a piece of butter. The cut bone released most of the suture tension and the tendon would withdraw itself from the shoulder.

The next securing devices used by surgeons were staples (Robertson, Daniel, & Biden, 1986). This device achieves tendon fixation by means of compression or driving a two prong staple through the tendon and into the bone (Goble et al., 1994; Shall &

Cawley, 1994). Surgery using this technique could result in the staple coming loose and dislodging from the bone (Hecker & Shea, 1993; Robertson et al., 1986). Concerns were raised because a loosened staple would act as a foreign object that could injure other parts of the shoulder (Craft et al., 1996).

In 1985, the first suture anchor was developed. The anchor is known today as the Statak anchor 5.0 mm by Zimmer Inc., Warsaw, IN (Craft et al., 1996; Goble et al., 1994). The anchor looked like a metal screw because it had a long shaft with threads running from the top to bottom of the device. The suture is attached to the anchor at the top of the device. The idea was to drive the anchor into the bone while the threads held the anchor in place. The suture then tied on to the ruptured tendon.

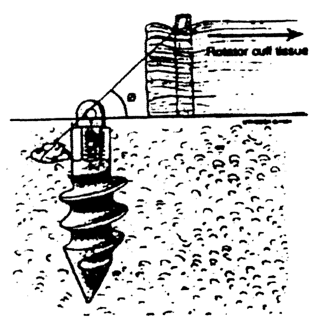

Figure 3. The deadman system to suture anchor.

Burkhart (1995) made comparisons between the suture anchor and the deadman method used to hold up a fence post as shown in Figure 3. The deadman is a rock that is buried in the ground. One side of a rope is tied to the rock and the other end of the rope is tied to a fence post at a forty five degree angle. The anchor resembles the secured rock, the suture symbolizes the rope, and the fence post shadows the tendon.

Since the design of the first anchor, surgeons have seen the anchor evolve into screw anchors, non-screw anchors, mini-anchors, and bioabsorbable anchors.

2.1 Screw Anchors

Screw anchors resemble common screws. Almost all screw anchors have an eyelet hole on the top of the anchor, followed by a threaded shaft. Screw anchors bore and secure into bone, regardless if an insertion hole has been drilled first. The insertion hole is created by hand or drill force. The minor hole diameter is the shaft size whereas the major hole diameter is the width. The threads tap into the bone like a nut rotating around a bolt. Barber et al. (1996) believed that large sized screw anchors were strongest because of the increased surface area on the screw threads.

The screw anchor is the oldest of all anchors and much research has been performed on the characteristics of these anchors. Some findings are: 1) pullout strength of a screw is enhanced when the thread diameter is large relative to the core diameter, according to research by Burkhart (1997a); 2) a study by Barber et al. (1995) concluded that larger screw anchors resulted in higher mean failure strengths; and 3) bone compaction with self-tapping compressing screws, increases the security of the anchor in bone (Burkhart, 1997a).

In two different studies by the same authors (Barber, Click, & Morley, 1995; 1996), the major and minor diameters of screw anchors were used as insertion holes. The minor diameter represented the dimension of the core shaft and the major diameter represented the width of the threads. A positive relationship was found between minor diameter and mean pullout strength. Examples of popular screw anchors include the

Corkscrew 5.0 and 3.5, Fastin 4.0, Ogden 5.5 and 3.5, Questus 5.0 and 3.5, Large Revo, and the Statak 5.2, 5.0, and 3.5 suture anchors.

There are three bone areas commonly used for suture anchor testing (Barber, 1997). They are identified in Figure 4 (Tortora, 1995) as the diaphyseal cortex (diaphysis), metaphyseal cortex (metaphysis), and metaphyseal cancellous bone trough (spongy bone) territories.

The diaphyseal is the thickest testing area (3 to 4 mm compact bone) which makes up the bone shaft and protects soft yellow marrow. The metaphyseal cortex contains spongy bone (cancellous bone holding red marrow), which is protected by 1 to 2 mm thick compact bone. It is located between the head of the humerus and the diaphyseal bone region. The metaphyseal cancellous or sponge bone trough is created by shaving a groove into the metaphyseal cortex simulating a common area used in rotator cuff repair.

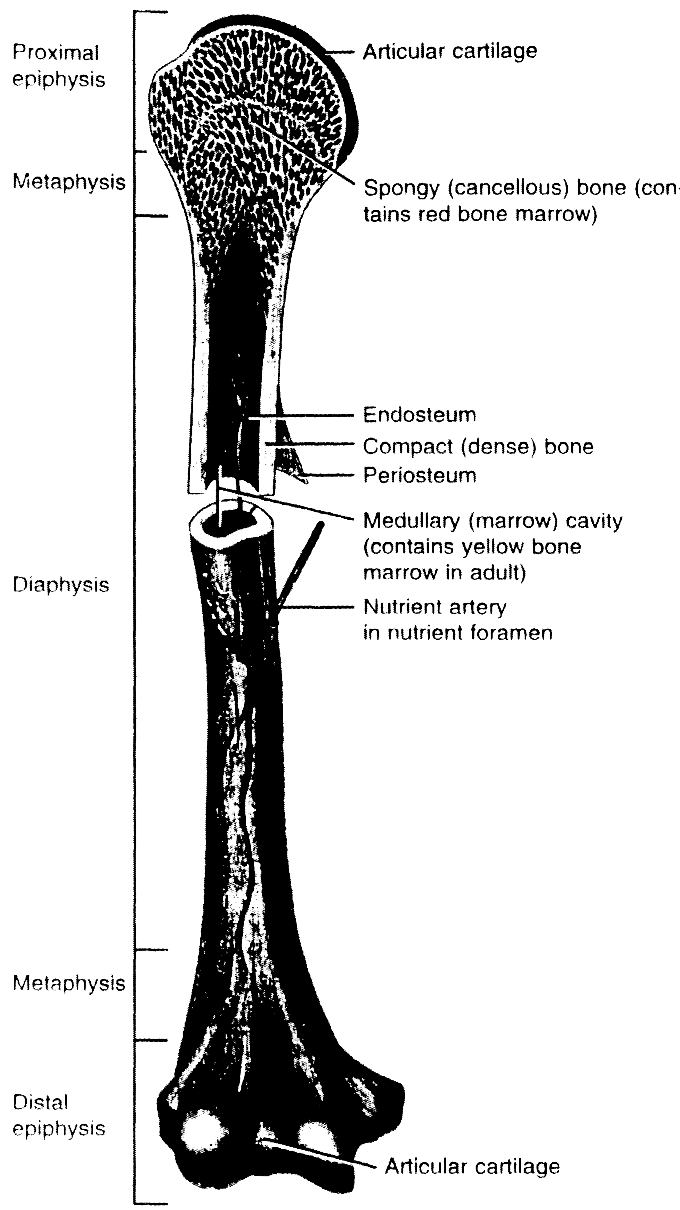

Figure 4. Diagram of a long bone showing suture anchor testing areas.

Pullout strength test involved the insertion of various anchors according to the manufacturers' directions. Once inserted, the anchor was evaluated perpendicularly to the bone surface using steel wire. The test measured the maximum tensile load for each of the anchors upon failure.

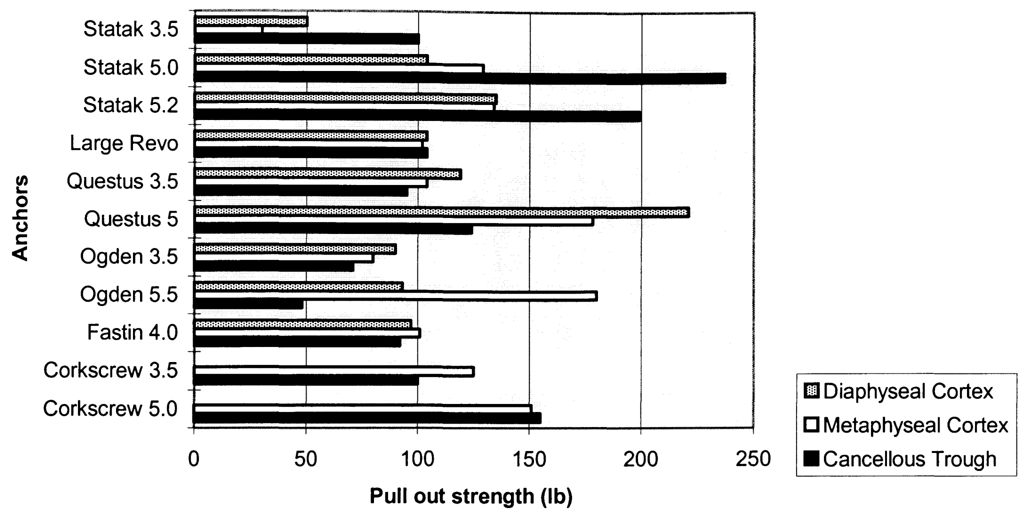

Figure 5. Pull out strengths of screw anchors.

Figure 5 shows the comparison of pullout strength of screw anchors using the following test bone regions: 3 to 4 mm thick bone diaphyseal cortex, 1 to 2 mm thick bone metaphyseal cortex, and metaphyseal cancellous bone trough which simulates rotator cuff repair. The metaphyseal cancellous trough region should be noted because an anchors performance is enhanced by insertion into better bone stock such as the humeral head where the bone mineral concentration is greatest (Barber, Click, et al., 1997).

Table 1 shows the anchor material, size (diameter and length), insertion hole diameter (minor and major), cancellous bone strength, and strength ranking (Barber & Cherf, 1997). Pullout strength tests were performed using the metaphyseal cancellous bone trough (spongy bone) territory since it simulates the bone region used in rotator cuff repair. Anchors in the same shaded regions are made by the same manufacturer.

Table 1. Screw Anchor Characteristics.

Anchor	Material	Size (mm)	Minor Hole (mm)	Major Hole (mm)	Cancellous Strength (lb)	Strength Rank
Corkscrew 5.0	Titanium alloy	5.0 by 15.5	1.4 to 2.1	5.0	155	3
Corkscrew 3.5	Titanium alloy	3.5 by 15.5	1.2 to 2.2	3.5	100	6 & 7 (tie)
Fastin 4.0	Titanium alloy	4.0 by 9.7	2.3	4.0	92	9
Ogden 5.5	Titanium alloy	5.5 by 12.0	3.5	5.5	71	10
Ogden 3.5	Titanium alloy	3.5 by 5.8	2.6	3.5	48	11
Questus 5	Titanium alloy	5.0 (diameter)	NA	5	124	4
Questus 3.5	Titanium alloy	3.5 (diameter)	NA	3.5	95	8
Revo	Titanium alloy	4.0 by 12.0	2.3	4.0	104	5
Statak 5.2	Titanium alloy	5.2 by 11.5	3.8	5.2	199	2
Statak 5.0	Titanium alloy	5.0 by 11.5	3.8	5.2	237	1
Statak 3.5	Titanium alloy	3.5 by 9.0	2.5	3.5	100	6 & 7 (tie)

The screw anchors listed in Table 1 are all made of titanium alloy. At room temperature, titanium forms a thin adherent oxide coating (TiO_2) (Groover, 1996). The coating provides excellent corrosion resistance. Because of the coating and its high strength, titanium is an ideal material for orthopaedic implants.

Corkscrew anchors resemble and function like a corkscrew. They are self-tapping and have small cores for easy hand insertion into the bone (Arthrex, 1998; Burkhart, 1997b). As shown in Table 1, the Corkscrew 5.0 has a holding strength of 155 lb. The minor screw insertion hole size for this anchor ranges between 1.4 and 2.1 mm, due to entry point widening as core shaft goes upward. The major diameter is 5.0 mm which equals to the thread width. A unique characteristic about the Corkscrew 5.0 anchor is that it can either secure one USP #5 suture or two #2 sutures. An anchor that can secure two sutures provides safety if one of the sutures happens to break.

The Corkscrew 3.5 has a minor insertion hole size ranging from 1.22 to 2.21 mm and a 3.5 mm major diameter. The anchor is comparable to the Statak (3.5). Both anchors have the same major insertion hole diameter of 3.5 mm. Their pullout strengths were similar as shown in Table 1, tying sixth and seventh places with a strength of 100 lb. Since both Corkscrew anchors are self-tapping, insertion holes are hand forced.

The Fastin 4.0 anchor from Mitek can be seen in Figure 6 (Mitek Products, 1998a). The anchor has a short body with deep threads that secure it into the bone allowing decent holding strength. Insertion involves a power drill which screws in the self-tapping anchor. The Fastin 4.0 has a major diameter of 4.0 mm, minor diameter of 2.3 mm, and a thread depth of 0.9 mm. The core and thread diameter broaden as the anchor goes upward. The Fastin suture anchor pierces the bone with the smaller tip creating a small incision (2.3 mm minor diameter). The rest of the anchor is forced into the bone making the insertion hole larger (4.0 mm major diameter). An enlarged insertion hole could cause stress on bone. The Fastin can be used in the shoulder, knee, hand, wrist, foot/ankle, and elbow.

Figure 6. Fastin screw anchor.

Ogden 5.5 and 3.5 anchors by Orthofix, can handle multiple sutures at the same time, adding security and efficiency by reducing the need for other anchors. However, the two anchors had undesirable strength rankings in Table 1. Compared with other anchors, Ogden 5.5 was second to last with a strength of 71 lb, making the strength questionable for multiple sutures. The strength of Ogden 3.5 was only 48 lb, which is much lower than the Corkscrew 3.5, Statak 3.5, and Questus 3.5.

Barber, Feder, Burkhart, and Ahrens (1997) performed a study on the relationship of bone density and anchor failure using Ogden 3.5. The anchor failed at a strength comparable to sutures in the transosseous (bone tunnel) suture technique. The anchor pulled out every time using steel wire indicating that the anchor to bone interface was not secure. The cadaver testing models used for this study came from elderly individuals (average age, 80). Effects of osteoporosis and poor bone quality in older patients led to bone weakening.

Method of insertion for Ogden anchors involves drilling a hole and then screwing the anchor in with a surgical screwdriver. The initial drill bit sizes could not be found because they were not listed in literature. There is a difference of 2.0 mm between the major 5.5 mm and minor 3.5 mm diameters for the Ogden 5.5 anchor. The Ogden 3.5 has a minor diameter of 2.6 mm with a major diameter of 3.5 mm.

Questus 5 and 3.5 anchors by Wright Medical Technology, Inc., resemble small wood screws with large shafts, sharp end cones, and shallow threads (Wright Medical Technology, 1998). They are self-tapping anchors. Their applications include the wrist, hand, foot/ankle, knee, shoulder, and elbow. Questus 5.0 and the Questus 3.5 have diameters of 5.0 and 3.5 mm, respectively.

The Revo anchor by Linvatec Corporation, is screwed into a predrilled bone hole. The Revo anchor is a deep threaded anchor. There is a difference of 1.7 mm between the outside threads and inner core (4.0 major - 2.3 mm minor). If a small insertion hole is used, the large threads are forced to bury into the bone. This would fracture thin or brittle bones.

Most pullout tests with Revo anchor indicate that the anchor fails at the eyelet or the suture hole (Barber et al., 1995). An accomplishment that the Revo had over other anchors in this study was consistency. The Revo was the most consistent (small standard deviation) of all anchors tested, showing very uniform pullout strengths in all test environments in spite of variations in bone densities.

However, another study found that initial repairs performed with the Revo anchor were significantly weaker than repairs even using the transosseous technique (Craft et al., 1996). This study confirmed that the sharp angle of the suture eyelet was indeed the reason why lower strengths were observed for this anchor.

The original Statak anchor 4.8 mm by Zimmer Inc., was the first screw anchor developed in 1985 (Goble et al., 1994). Since then, the anchor has been modified and is now known as the Statak 5.0 mm. The Statak 5.0 has superb strength of 237 lb as shown in Table 1, in comparison to other anchors. The 3.8 mm minor hole size and 5.2 mm major hole size results in a 1.4 mm difference, distinguishing deep threads for outstanding bone fixation.

Figure 7. Statak screw anchors.

Figure 7 shows Zimmer Statak anchors made of titanium alloy (Barber & Cherf, 1997). The anchors are easy to place in the bone with drilling, tapping, and countersinking completed in a single procedure using a power tool (Carpenter et al., 1993). The anchors can be used in the shoulder, foot/ankle, elbow, wrist, hand, and knee.

Roth et al. (1998) studied the effects of cortical bone thickness on Statak 3.5 anchor. The anchor was experimented using 0.45 mm steel wire. The anchor failed at an average of 28.8 lb when implanted into 1.3 mm thick bone and at 13.3 lb when implanted into 0.7 mm thick bone. The anchor pulled through cancellous bone and came to rest against the inner cortex during submaximal load cycling. The anchor settled and the pullout test followed. The study concluded that thicker bone cortex increased the ultimate pullout strength of anchors and allowed more load to be applied during the period of rehabilitation.

Statak 5.2 anchor has a diameter of 5.2 mm and a length of 11.5 mm (major-5.2 and minor-3.8). Berlet, Johnson, Milne, Patterson, and King (1998) evaluated the Statak anchor 5.2 and determined that it performed very well. Its strength surpassed that of the transosseous suture bone tunnel technique. In Table 1, Statak 5.2 anchor ranked second overall with a strength of 199 lb.

Ticker, Lippe, Barkin, and Carroll (1996) discussed a surgery that involved Statak suture anchors. In 1995, they reported the first case of infected suture anchors in the shoulder. Eight weeks after surgery, a patient experienced elevated body temperatures. X-ray did not reveal any problems. Retrieval surgery was performed and it was noticed that the anchors were loose and easily released by pulling on the attached nonabsorbable sutures. The holes released fluid indicating infection. Antibiotics were administered to fight off the infection along with intense physical therapy and the patient fully recovered. The exact cause of the infection was not determined to be related to the Statak anchors. Ticker et al. (1996) established that anchors were forced or pressed into bone for fixation may cause damage to the bone if removed. They also felt that an anchor designed to be removable and can be screwed into place, may be desirable for both intraoperative and postoperative considerations. Screw anchors can be removed by unscrewing.

Insertion holes take the shape of the driven screw anchor. It is assumed that the insertion hole size will be determined by the exerted rotational force, core, and thread diameter of the given screw anchor. Forceful insertion can cause stress on bone especially when using trapezoid shaped metal anchors. The bone thickness and quality are also factors (Barber et al., 1996), since anchor performance is enhanced by insertion into better bone stock (Barber, Feder, et al., 1997; Roth et al., 1998). The threads remove material and dig deeper into the hole, pushing the anchor farther in. Screw anchor insertion methods and sizes (e.g., minor and major diameters) should be evaluated further in terms of bone effects and anchor strengths.

2.2 Non-Screw Anchors

After the introduction and evolution of the screw anchor, companies started to design non-screw anchors. The toggle type suture anchor belongs to this family of anchors. As their names suggest, most of these anchors do not resemble the screw design. Non-screw anchors vary drastically on their mechanical features. Some anchors expand in width (e.g. GII by Mitek) upon insertion and others function as a wedge (e.g., Harpoon by Arthrotek, Inc.).

Most of the anchors require that an insertion hole be created first. Then insertion can take place by injecting the anchor into the hole using an introduction device. Barber et al. (1995; 1996) tested non-screw anchors using predetermined hole sizes. Insertion hole sizes significantly affect the performance of anchors. It was noted that large insertion holes for non-screw anchors resulted in lower mean pullout strengths in the humeral head. Various examples of non-screw anchors include Anspach, Harpoon, GII, Super Anchor, Rotator Cuff Anchor (RCA), Multitak SS, SB 3.0, PeBA 5.0, Roc 2.3, Roc 2.8, Roc 3.5, Roc XS, and the Utrafix.

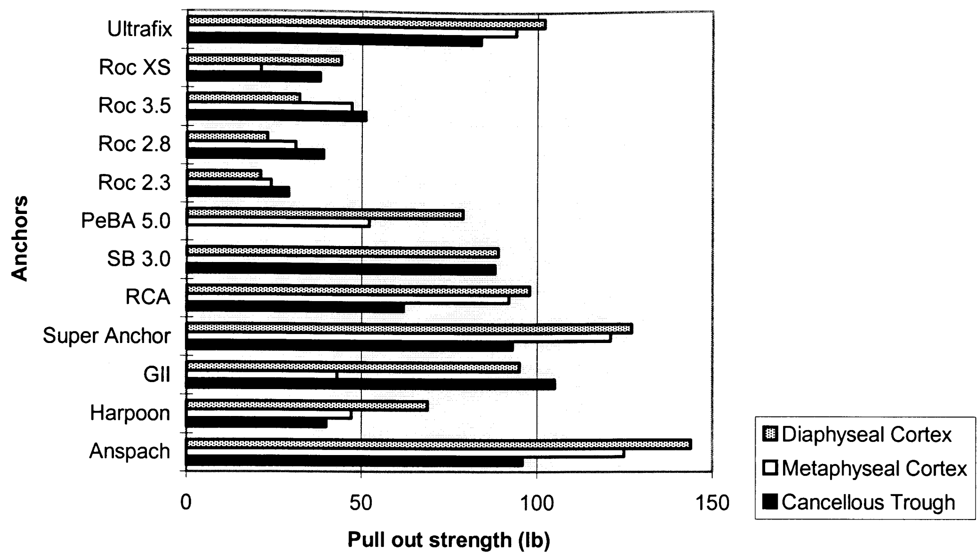

Figure 8. Pull out strengths of non-screw anchors.

Figure 8 shows comparison of pullout strength for non-screw anchors. The test regions were the same as in Figure 5. Table 2 summarizes the anchor material, size (diameter and length), insertion hole diameter, cancellous bone strength, and strength ranking (Barber & Cherf, 1997). Comparison on pullout strength was performed using the metaphyseal cancellous bone trough territory since it simulates the bone region used in rotator cuff repair. Anchors in the same shaded regions are made by the same company.

Table 2. Non-Screw Anchor Characteristics.

Anchor	Material	Size (mm)	Insertion Hole (mm)	Cancellous Strength (lb)	Strength Rank
Anspach	Titanium alloy	2.6 (diameter)	3.1	96	2
Harpoon	316L stainless	3.2 (diameter)	3.2	40	8
GII	Titanium and Nickel	2.4 by 8.8	2.4 by 14.2 (depth)	105	1
Super Anchor	Titanium and Nickel	2.9 by 11.4	2.9 by 17.8 (depth)	93	3
RCA	Titanium and Nickel	2.9 by 9.2	2.9 by 17.8 (depth)	62	6
Multitak ss	316L stainless	3.0 by 6.0	3.4	NA	NA
SB 3.0	Titanium alloy	3.0 (diameter)	3.0	88	4
PeBA 5.0	Titanium alloy	5.0 (diameter)	3.2 (minor) by 4.0 (major)	NA	NA
Roc 2.3	Polyethylene and acetal	2.3 by 5.0	2.3 by 6.2 (depth)	29	11
Roc 2.8	Polyethylene and acetal	2.8 by 10.0	2.8 by 14 (depth)	39	9
Roc 3.5	Polyethylene and acetal	3.5 by 10.0	3.5 by 14 (depth)	51	7
Roc XS	Acetal	3.5 by 8.2	3.5 by 14 (depth)	38	10
Ultrafix	316L stainless	2.9 (diameter)	3.2	84	5

Besides titanium, stainless steel (e.g. 316L) is a common material for suture anchors as shown in Table 2. Stainless steels are strong and designed to provide high corrosion resistance (Groover, 1996). Chromium, the principal alloying element in stainless steel, forms a thin oxide film which protects the surface from corrosion.

Anspach Anchor system is by Anspach Effort, Inc. This anchor is similar to a dry wall anchor since it opens after insertion. The drill hole size is 3.1 mm, larger than the initial anchor diameter of 2.6 mm. After it is inserted, it expands in width to 7.2 mm.

The anchor amplifies wide enough to clog the hole. The anchor is able to hold two prethreaded USP #2 sutures, with ranking second in pull strength in Table 2.

The Harpoon anchor from Arthrotek, Inc., is modeled after a harpoon. Insertion of the Harpoon anchor involves impacting the prethreaded anchor into the bone with the use of a mallet (Arthrotek, 1996). The Harpoon is designed to function as a wedge causing bone stress to develop upon insertion. This stress would be detrimental to thin or brittle bones. This anchor can hold a larger suture of 0.7 mm diameter, whereas most anchors can only hold a suture of 0.5 mm.

Figure 9 shows the GII anchor made of titanium or NiTi (nickel and titanium) by Mitek (Mitek Products, 1998b). It has two NiTi arcs which spring outward, causing the width of the anchor to expand after it is inserted. Nitinol Medical Technologies, Inc. (1998) claims that the NiTi material has a blood clotting time of around eight minutes which is similar to blood clotting on its own. On the contrary, 316L stainless steel has a faster blood clotting time of six and a half minutes.

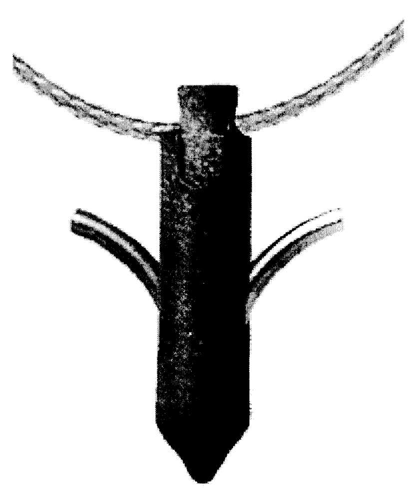

Figure 9. GII non-screw anchor.

GII was first introduced in 1989 only for shoulder surgery and now it can be used in over twenty different areas in the body (Nitinol Medical Technologies, 1998). The anchor is small and strong. It has a diameter of 2.4 mm and a length of 8.8 mm (Mitek Products, 1998b). In Table 2, the GII showed the highest cancellous strength of 105 lb. Like the Statak screw anchors, there have been extensive research results on the GII since it was one of the first pioneer anchors (Barber, 1997; Barber & Cherf, 1997; Barber et al., 1993; Barber et al., 1995; Barber et al., 1996; Berlet et al., 1998; Carpenter et al., 1993; Mologne, McBride, & Lapoint, 1997; Roth et al., 1998; Wetzler et al., 1996).

According to a study by Wetzler et al. (1996), during the initial 20 percent of cycles (sometimes during the first 10 cycles), the GII anchor would settle, breaking through the spongy bone and coming to rest on the inner surface of the compact bone. Wetzler et al. added that many orthopaedic surgeons have experienced the displeasure of seeing a portion of the suture anchor exposed after being cycled and loaded only a few times immediately after insertion.

The Super Anchor by Mitek, as shown in Figure 10, uses four NiTi arcs for maximum strength while maintaining a small size (Mitek Products, 1998e). The four arcs also create an equal placement of the anchor in the predrilled insertion hole because the arcs are arranged so that they deploy equally in a three hundred and sixty degree radius. The Super Anchor can accommodate one large suture or even multiple sutures at the same time as indicated by its strength in Table 2 (#3, 93 lb).

Figure 10. Non-screw Super Anchor.

Tauro (1998) recommended that the number of anchors necessary is one anchor for each centimeter of tendon tear using Super Anchors. In research by Fennell, Ballard, Pflaster, and Adkins (1996), Super Anchors using USP #1 suture failed comparably to the transosseous bone tunnel technique. Both systems failed by suture laceration. Yet, the same study tested Super Anchors using USP #5 suture and concluded that it was superior to bone tunneling. Pullout strength lessened at the tendon to suture interface. This indicates that USP #1 suture was the reason the anchor failed for the first tests. Failure of the tendon in the second tests showed that the anchor to bone interface was strong.

The Rotator Cuff Anchor (RCA) also by Mitek, is seen in Figure 11 (Mitek Products, 1998d). This anchor was designed to be used in rotator cuff repair. Like the GII and the Super Anchor, the Rotator Cuff Anchor is inserted into the bone and the two

NiTi arcs spring outward causing the diameter to expand. The RCA has a trocar tip so that it can pierce through the bone. Thus it does not need predrilling for insertion.

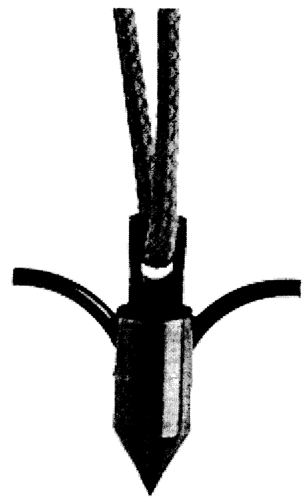

Figure 11. Non-screw Rotator Cuff Anchor (RCA).

The Multitak SS large anchor (3.0 mm in diameter) by Bonutti Research Inc., is made of 316L stainless steel (Bonutti Research, 1997). It is a cylinder shaped toggle type anchor. A hole is drilled into the bone before insertion. The anchor has an insertion hole of 3.4 mm. The insertion hole is bigger than the diameter of the anchor so the anchor and USP #2 suture (0.5 mm) can enter at the same time.

The anchor is inserted perpendicularly into the bone using a device similar to a push button pen, as seen in Figure 12. Once the anchor is injected completely into the bone, the surgeon toggles the anchor using the rear end as a pivot point catching bone or marrow. The cylinder rotates ninety degrees causing the anchor to lay parallel to the inner bone cortex. The anchor sits inside the bone eliminating exposure. The pullout strength for steel wire was unavailable. However, the average pullout load is 30.1 lb with USP #2 suture (Bonutti Research, 1997).

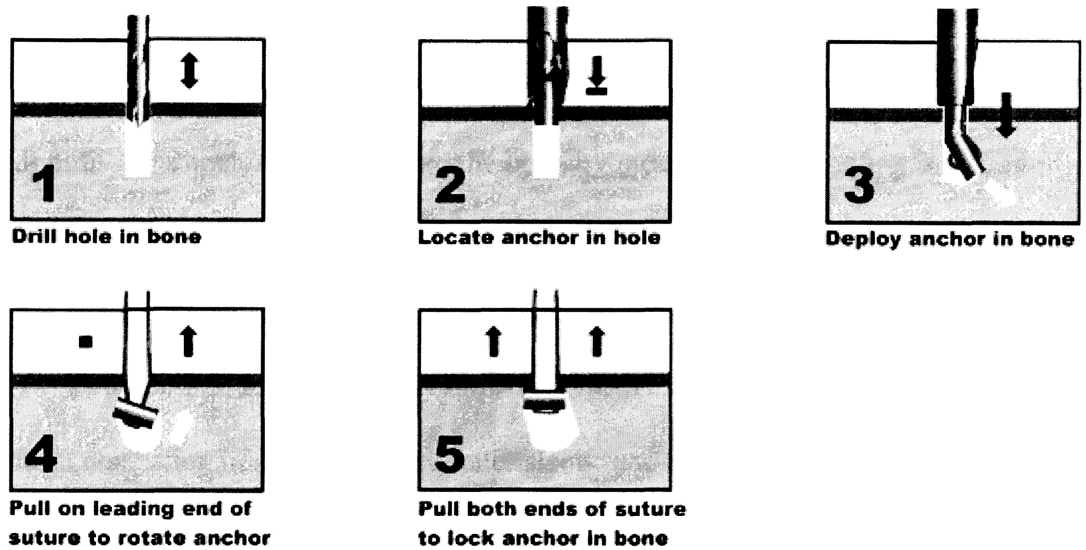

Figure 12. Insertion procedure for the Bonutti Multitak SS toggle type suture anchor.

The SB 3.0 and PeBA 5.0 anchors are both made of titanium alloy, by Orthopaedic Biosystems Ltd. The SB 3.0 is a parallelogram shaped cylinder with a large suture eyelet running through its center, making it a toggle type suture anchor (Skiba, 1998). The SB 3.0 is inserted into a 3.0 mm predrilled hole and the surgeon toggles the anchor into position.

Research on the SB 3.0 toggle anchor suggested that it was difficult to insert because of inaccurate introduction (Barber, Click, et al., 1997). The diameter and the insertion hole of the anchor is 3.0 mm. Insertion involves introducing the anchor and the suture simultaneously. The hole size might make insertion difficult since there is little clearance for the anchor. Forcing the suture into the hole will cause suture pinching and fraying, wearing down the strength.

The PeBA 5.0 is an anchor which might resemble a screw anchor. There are single rings running from the large head to the bottom of the anchor on a narrow shaft. The anchor has a 3.2 mm minor hole and a 4.0 mm major hole whereas the anchor width is 5.0 mm. This anchor is forced into the bone by means of an impacting insertion device. The single rings clog the hole and secure the anchor at the same time. Since this anchor has an oversized suture eyelet, it can accommodate up to two sutures.

The Roc 2.3, 2.8, and 3.5, by Innovasive Devices, Inc., are all made of the same material consisting of a polyethylene outer sleeve and an acetal inner pin. The exception is the Roc XS (initial core diameter of 3.5 mm), which is made of acetal only. To insert these anchors, a hole must be drilled or punched into the desired bone area. Then the anchor is inserted using an insertion gun. The gun actually deploys or makes the anchor diameter spring outward in width, making it plug the insertion hole.

The Roc 2.3 is limited to the wrist and hand because it is small. Both the Roc 2.8 and 3.5 can be used in shoulder, knee, ankle, foot, and wrist surgeries. The Roc XS has been strictly designed to be used in the shoulder. In Table 2, the Roc anchors did not place well (7, 9, and 11 overall in strength ranking). Polyethylene is not very strong compared to metal, which might be a reason for low pullout strength.

The Ultrafix anchor by Li Medical Technologies, Inc., is made of 316L stainless steel. The anchor has a diameter of 2.9 mm and an insertion hole size of 3.2 mm. This anchor is inserted as a smooth cylinder and then opens with eight spikes securing it to the bone (Barber & Cherf, 1997). The larger insertion hole allows clearance (3.2 - 2.9 = 0.3

mm) for the diameter to expand. This anchor can be used practically all over the body because of its size and security of the spikes.

Non-screw suture anchors are a valuable means of securing soft tissue to bone. Most insertion holes are created by predrilling or impacting. According to information by Wetzler et al. (1996), the initial strength is related to the quality and thickness of the bone, the suture used, and the design of the suture anchor (Barber, Feder, et al., 1997; Roth et al., 1998).

The anchor induced stress on the bone due to insertion has to be considered. Deploying anchors expand drastically in width. This feature clogs the hole and places stress on the bone at the same time. Barber et al. (1993) have also insinuated that the ultimate pullout strength of a suture anchor is not markedly diminished over time. Roth et al. (1998) and Wetzler et al. (1996) attested that suture anchors were exposed to an increasing number and magnitude of submaximal loads during rehabilitation, which means soft tissue healing and mechanical failure of the anchor systems is progressively being pushed to the limit. An effective insertion hole needs to securely interface with the anchor so that the anchors strength will not diminish with submaximal load and time.

2.3 Mini-Anchors

Mini-anchors were the next family of suture anchors to evolve after non-screw anchors. They are defined as having drill holes or minor diameters less than 2.2 mm (Barber, Click, et al., 1997). Many manufacturers want to produce small anchors that can be used in small bones (e.g. hand, foot, and elbow). These anchors usually can support a suture with a diameter size of 0.5 mm or smaller.

The mini-anchors can be either a screw or non-screw type. Their mechanical characteristics are similar to the larger anchors. A study conducted on mini-screw anchors reported that they usually fail at the anchor eyelet due to wire breakage (Barber, Click, et al., 1997). The eyelets for mini-screw anchors are small and thin causing a sharp angle for the wire to loop around (e.g. like looping suture on a dull knife). The study also stated that non-screw mini anchors failed usually by anchor pullout. Non-screw mini anchors have limited surface area (e.g. small threads and barbs) to secure into the bone.

The mini-screw anchors include: Statak 1.5 and 2.5, the Questus 2.5, the Mini-Revo, the Fastin 3.0, and the Ogden 2.5. The non-screw mini anchors include: Mini harpoon, PeBA 3.0, Multitak SS small anchor, SB 2.0 mm, and the Mini Mitek.

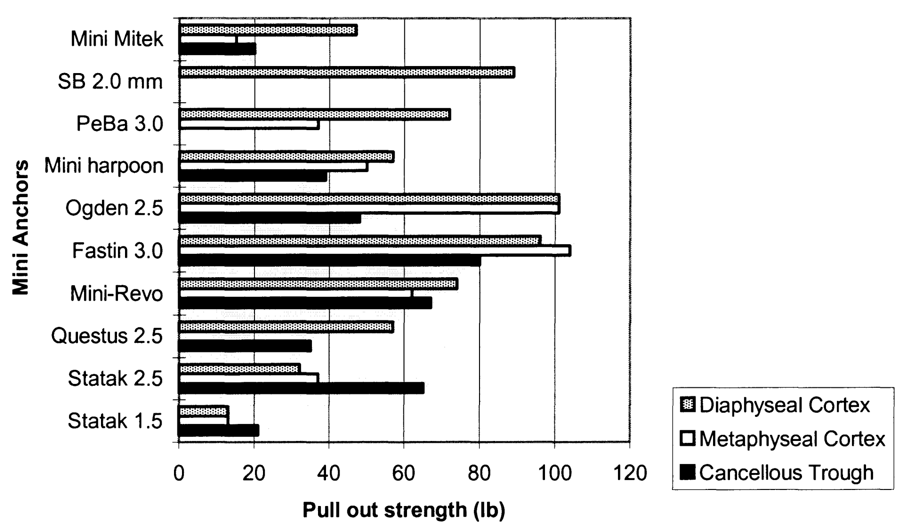

Figure 13. Pull out strengths of mini-anchors.

Figure 13 shows a comparison of pullout strength for mini-anchors. Pullout strength test involves the insertion of the various anchors according to the manufacturers directions. Once inserted, the anchor is pulled out of the bone using wire suture. The test then measures the maximum pullout strength for each of the anchors upon failure. Tests were conducted at diaphyseal cortex of 3 to 4 mm, metaphyseal cortex of 1 to 2 mm, and the metaphyseal cancellous bone trough which simulates the bone area used for rotator cuff repair.

Table 3. Mini-Anchor Characteristics.

Anchor	Material	Type	Size (mm)	Insertion Hole (mm)	Cancellous Strength (lb)	Strength Rank
Mini harpoon	316L Stainless Steel	Non-screw	2.0 diameter	2.0	39	4
Mini Mitek	Titanium & Nickel	Non-screw	1.8 diameter	1.8 by 9.7 depth	20	7
Mini-Revo	Titanium alloy	Screw	2.7 diameter	1.8 minor by 2.6 major	67	1
Ogden 2.5	Titanium alloy	Screw	2.5 by 4.1	2.1 minor by 2.5 major	48	3
PeBA 3.0	Titanium alloy	Non-screw	3.0 diameter	1.8 minor by 2.1 major	NA	NA
SB 2.0	Titanium alloy	Non-screw	2.0 diameter	2.0	NA	NA
Questus 2.5	Titanium alloy	Screw	2.5 diameter	1.8 minor by 2.5 major	35	5
Statak 1.5	Titanium alloy	Screw	1.5 diameter	0.8	21	6
Statak 2.5	Titanium alloy	Screw	2.5 by 7.5	1.7 minor by 2.5 major	65	2

Table 3 shows the anchor material, type (screw or non-screw), size (diameter and length), insertion hole diameter (minor and major if applicable), cancellous strength, and strength ranking (Barber & Cherf, 1997). Pullout strengths were compared on the metaphyseal cancellous bone trough territory since it simulates the bone region used in rotator cuff repair.

Barber et al. (1995) encountered some difficulties with Statak 1.5 during testing. The torsional force necessary to screw the anchor into all three bone regions (3 to 4 mm diaphyseal cortex, 1 to 2 mm metaphyseal cortex, and metaphyseal cancellous bone trough) exceeded the strength of the screw hub causing it to shear off. The design of the hub and screw interface weakened the performance of the anchor.

2.4 Bioabsorbable Anchors

Bioabsorbable anchors are made of materials that the body is able to break down over a long period of time. Barber and Deck (1995) explain that this characteristic would minimize the problems of anchor loosening, migration, interference with imaging studies, and the potential requirement for later implant removal. A bioabsorbable material for anchors must be nontoxic and well tolerated by the host, with no immune reaction (Simon, Di Cesare, & Ricci, 1997). Strength and elasticity are also very important qualities required for a bioabsorbable anchor to succeed. Middleton and Tipton (1998) stated that an ideal polymer would remain strong until surrounding tissue is healed, is metabolized in the body after fulfilling its purpose, is easily processable into the final product, demonstrates acceptable shelf life, and is easily sterilized.

The development of bioabsorbable fixation devices has focused on a group of polymers known as alpha-polyesters or poly (alpha-hydroxy) acids (Simon et. al., 1997). Some examples include polyglycolic acid (PGA), polylactic acid (PLA), and polydioxanone (PDS). Sutures made of PGA lose about fifty percent of their strength after two weeks and one hundred percent at four weeks, and are completely absorbed in four to six months (Middleton & Tipton, 1998). Poly L-lactic acid (PLLA) is a suture anchor bioabsorbable material. According to research by Barber and Deck (1995), the half life of PLLA is six months. The complete degradation time for PLLA is more than two years (Middleton & Tipton, 1998). The absorbed PLLA is recycled by conversion to glycogen in the liver where it becomes incorporated into carbon dioxide and water so that it can be excreted by the lungs (Simon et al., 1997).

A twelve week period is sufficient for the shoulder bone to heal, speculating that the tendon is attached to the bone. After surgical repair and rehabilitation, the bone marrow will absorb the biodegradable material over time. The healed area in the bone will show no trace that an anchor ever existed.

Bioabsorbable anchors are gaining attention. They are ideal for orthopaedic surgery because they will be eventually absorbed. According to Middleton and Tipton (1998), much care is needed for bioabsorbable plastics. Material, molecular weight, suture anchor size, water absorption, sterilization, storage, and processing can affect the degradation rate of bioabsorbable suture anchors (Simon et al., 1997).

Bioabsorbable anchors can be classified in all three categories including screw, non-screw, and mini-anchors. Some examples of screw anchors would be the Biologically Quiet Mini-Screw and the Bio-Statak. Non-screw anchors would include the Bio-Anchor, Panalok, Bionix Shoulder, and GLS (made of poly L lactic acid and has nonabsorbable NiTi arcs).

Figure 14 shows anchor strength comparisons among various bioabsorbable anchors. Pullout strength test involves the insertion of the various anchors according to the manufacturers directions. Once inserted, the anchor is pulled out of the bone using suture. The maximum pullout strength for each anchor upon failure is measured. Tests were conducted at diaphyseal cortex of 3 to 4 mm, metaphyseal cortex of 1 to 2 mm, and the metaphyseal cancellous bone trough which simulates the bone area used for rotator cuff repair.

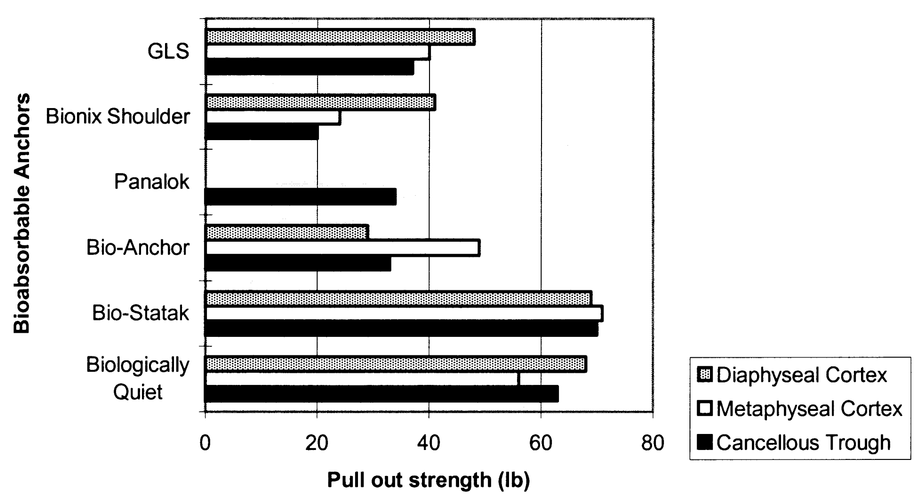

Figure 14. Pull out strengths of bioabsorbable anchors.

Table 4 summarizes the anchor material, type (screw or non-screw), size (diameter and length), insertion hole diameter (minor and major if applicable), cancellous strength, and strength ranking (Barber & Cherf, 1997). The comparison was made on the metaphyseal cancellous bone trough territory since it simulates the bone region used in rotator cuff repair. Anchors are separated using shaded regions to distinguish different manufacturers.

Table 4. Bioabsorbable Anchor Characteristics.

Anchor	Material	Type	Size	Insertion Hole (mm)	Cancellous Strength (lb)	Strength Rank
Bio-Anchor	PLLA	Non-screw	3.5 diameter	2.1	29	5
Biologically Quiet	DLGA	Mini-screw	3.81 by 15.0	3.2	63	2
Bionix Shoulder	PLLA	Non-screw	3.2 outer diameter	3.2	20	6
Bio-Statak	PLLA	Screw	5.0 by 12.0	2.5 to 3.6 minor & 5.0 major	70	1
GLS (not fully absorbable)	PLLA and NiTi	Non-screw	2.9 by 9.5	2.9 by 17.8 (depth)	37	3
Panalok	PLLA	Non-screw	NA	NA	34	4

Biologically Quiet mini-screw suture anchor by Instrument Makar, Inc., is made of eighty five percent (D, L) lactide and fifteen percent glycolide. Research by Barber and Deck (1995), implied it was possible to increase the degradation rate without greatly affecting the initial mechanical properties by the introduction of a few D-units (Poly D-lactic acid) within the L-units in the PLLA chains. Studies have shown that the Biologically Quiet screw has no adverse effects or bone cyst formation (Instrument Makar, 1997). The anchor takes about twelve weeks to absorb and is then replaced by normal marrow and outer bone. Bench testing showed the Biologically Quiet screw was comparable to existing metal suture anchors in resistance to pullout from bone.

Another bioabsorbable screw anchor is the Bio-Statak by Zimmer. The anchor is made of poly L-lactic acid. The size of the anchor is 5.0 by 12.0 mm, which is similar to the Biologically Quiet screw. Method of insertion involves drilling and taping the hole in one step. This anchor can be used for shoulder, foot/ankle, elbow, wrist, hand, and knee repairs.

Bio-Anchor by Linvatec Corp. is a non-screw mini bioabsorbable anchor on the market. The diameter of this anchor is 3.5 mm and the insertion hole is 2.1 mm. The anchor is inserted by compaction. There is a 1.4 mm difference between the diameter of the anchor and the insertion hole. This puts much stress on the bone to fit the anchor. The anchor is made of poly L-lactic acid and can be used to secure ligaments, tendons, and soft tissue to the shoulder bone.

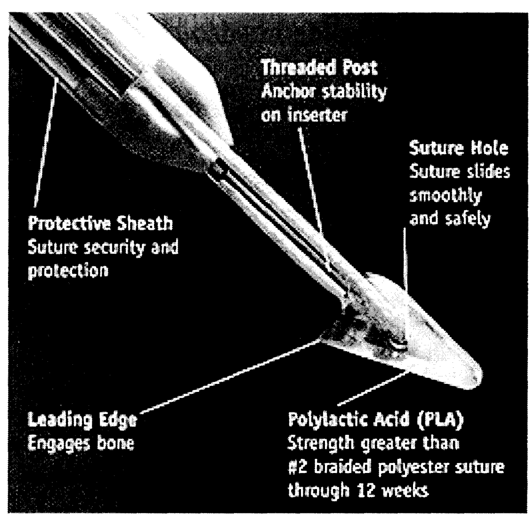

Figure 15. Toggle type Panalok bioabsorbable anchor.

Panalok is another non-screw bioabsorbable anchor made of PLA, which is a toggle type suture anchor as seen in Figure 15 (Luscombe et al., 1997; Mitek Products, 1998c). It looks like a wedge from the side but flat from the bottom and top views. The objective is to insert the anchor with the tip of the wedge guiding it into the predrilled bone hole. Then the rest of the anchor will follow when a pushing force is applied. Once the whole anchor is inside the insertion hole, toggling should be done quickly so that tension causes the anchor to lock itself within the bone hole. Other non-screw bioabsorbable anchors include: Bionix Shoulder by Bionix, Inc. (self-reinforced poly L lactic acid) and the GLS by Mitek (poly L lactic acid, NiTi gull wing not absorbable).

As a group, bioabsorbable anchors held the lowest strength. The metal screw anchors group held the highest strength, followed by the metal non-screw anchors, and then by the mini-anchors. All groups are able to secure in bone and attach tissue effectively.

Overall, the screw design seems to be stronger than the non-screw design for all groups. In the mini-anchors and the bioabsorbable anchors, the screw anchors ranked higher than the non-screw anchors according to Tables 3 and 4. Nonetheless, Table 2 shows that non-screw anchors also have respectable strengths. Most screw anchors create insertion holes by self tapping. Non-screw anchors either impact, deploy, or toggle.

For non-screw anchors, predrilling an insertion hole is critical. There is a need for further exploration to establish optimal insertion hole diameters to improve the performance of non-screw anchors.

CHAPTER 3

Methodology

3.1 Suture Anchor

This study involves toggle type anchors of cylinder shape. The anchor has two suture holes running perpendicularly through its axis as shown in Figure 16. It is designed to be inserted length ways into the bone through a predrilled insertion hole, with the rear end of the anchor acting as a pivot point. After insertion, this pivot point catches bone or marrow and causes the anchor to maneuver 90 degrees or to lay parallel to the surface of the bone after the surgeon has toggled the suture.

Four cylinder shaped toggle type anchors were studied for this research. They included: 1) small cylinder anchor type A; 2) small cylinder anchor type B; 3) large cylinder anchor type A; and 4) large cylinder anchor type B. The type B anchors evolved from the designs of type A anchors.

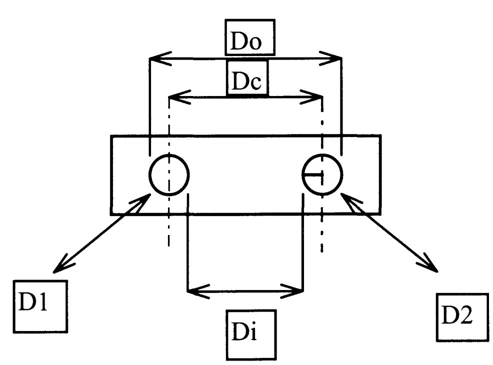

Figure 16. Schematic of the cylinder shaped toggle type anchor.

Table 5. Cylinder Shaped Toggle Type Anchor Dimensions.

Anchor Type	Length (mm)	Diameter (mm)	Do (mm)	Dc (mm)	Di (mm)	D1 (mm)	D2 (mm)
Small A	3.70	1.80	2.40	1.52	0.635	0.889	0.889
Small B	3.70	1.80	2.40	1.52	0.635	0.889	0.889
Large A	6.00	3.00	3.43	2.54	1.65	0.889	0.889
Large B	6.00	3.00	3.71	2.54	1.37	1.17	1.17

Table 5 shows dimensions of the four types of cylinder shaped anchors used for this research. The dimensions include the overall length, diameter, outside distance (Do), center distance (Dc), inside distance (Di), and two diameters (D1 and D2) of suture holes.

Small anchor type A is made of 316L stainless steel and has a hole running from one end of the cylinder to the other like a pipe. Small anchor type B is made of titanium alloy and does not have the center hole. Overall, these two anchors are very similar. The nominal dimensions for small anchors used for this study are 1.8 by 3.7 mm.

Large anchor type A is made of titanium alloy and has suture hole diameters (D1 and D2) of 0.889 mm. Large anchor type B is also made of titanium and has suture hole diameters (D1 and D2) of 1.17 mm. The overall dimensions for both anchors are 3.0 by 6.0 mm.

3.2 Suture

The suture used in the study was: USP #2; SP257, polyviolene, green braided, coated, nonabsorbable, non-sterile surgical suture, with a diameter ranging from 0.5 mm to 0.59 mm.

3.3 Experimental Conditions

The first model material used in this research was acrylic plate. The acrylic plate has a thickness of 6.35 mm (0.25 in.), which was cut in approximately 2 x 2 in. squares. Insertion holes were drilled into each individual plate with diameters from 2.1 to 2.6 mm for small anchors, and 3.3 to 3.7 mm for large anchors. Minimum insertion hole diameters were identified when the suture anchors were no longer able to fit or to be inserted. Once the smallest holes were determined, the insertion hole sizes were then increased (e.g. 2.3, 2.4, etc.) until the maximum hole sizes had been reached which would not cause anchor slippage.

Eight tests were performed using each individual acrylic plate for each insertion hole diameter. Anchors were reused since no apparent damages were observed on the anchors after testing. New suture was used for every test.

The other model for this study involved fresh pig shoulder bones. The fresh pig bones were obtained through Jennings' Meat Processing, Inc., Oakland, IL. Pig bones were chosen over cadaver bones since they can be freshly obtained while cadaver bones are usually frozen. Only two designs of cylinder shaped toggle type anchors were tested in the pig bones including small B and large B anchors.

Five tests for each insertion hole size were conducted on fresh pig bones. The reasons for fewer number of tests on pig bones were, 1) anchors cannot be retrieved after testing, and 2) the bone surface area on one bone can not accommodate more than five anchors for each hole size.

Five insertion holes were drilled into the bone (metaphysis region) for each hole size. Insertion holes were drilled into separate bones, starting with hole sizes of 3.4 mm.

After the first five tests were completed, insertion hole sizes were subsequently decreased using five more tests for each hole diameter. Testing proceeded until the suture anchors were no longer able to fit or be inserted in the bone. Once the smallest holes had been determined for each anchor, the insertion hole sizes were increased. The tests continued until the maximum hole size that would not cause anchor slippage had been reached. One bone was used for all insertion hole tests involving small type B anchors and another bone for large type B anchors.

Pull strength testing was performed using an Instron 4467 universal testing machine (Instron Corp., Canton, MA) in the Materials Testing Lab at Eastern Illinois University. Both models were tested using a holding device which secured directly to the lower fixture of the Instron testing machine. Individual plastic plates were placed flat on the holding device so that anchors were tested perpendicularly to the suture and actuator. Plates were secured to the holding device. The pig bone model was arranged in a vise that allowed bone movement so the anchor could be positioned directly under the cross-head. This allowed tensile loading to be parallel to the axis of anchor insertion for the bone model.

The Instron testing machine was setup using the following parameters.

- The speed or loading rate for testing the anchor was 75 mm min^{-1} (1.25 mm s^{-1}).
- A three inch gap was used between the top hook of the tester and the test piece.
- Once the anchor was setup for testing, two black dots were marked at the entrance of the suture before it entered the acrylic plate. The dots were used to identify locations of suture breakage.

3.4 Data Acquisition and Analysis

Eight test results for each insertion hole size using acrylic plates were recorded, averaged, and the standard deviation calculated. The same was done for the pig bones using five tests for each insertion hole size. For all tests, the suture appearance was noted if there were any rough spots or suture discoloration. Locations of failure were also noted.

Once all of the data was recorded, statistical analysis was performed. An analysis of variance (ANOVA) was used to determine if the insertion hole size significantly affected the pull strength of a cylinder shaped toggle type anchor in acrylic plate and bone. The ANOVA was performed using a SAS system.

3.5 Scanning Electron Microscopy (SEM) Observation

A variable pressure scanning electron microscope (Hitachi 3500N) in the Scanning Electron Microscopy Lab at Eastern Illinois University was used to further study the interaction between the suture and anchor. This invaluable observation facilitated understanding of causes which lead to the suture fracture. It also provided significant information to optimize the suture anchor design.

The suture anchor system was simulated using a specially designed fixture and tensile stage. Suture tension could be adjusted by turning a spindle attached to the tensile stage. The system was viewed in back scattering electron (BSE) with variable pressure mode, thus, the polymeric suture was observed as it was stretched, without any coating. An accelerating voltage of 25 .0 KV and a gas pressure of 50 Pa were chosen for this study.

CHAPTER 4

Presentation and Interpretation of the Data

4.1 Pull Strength and Design on the Suture Anchor System

4.1.1 Suture Strength

To provide a basic understanding on suture strength, eight tests were conducted on USP #2 suture. The tests were performed using an Instron universal testing machine by looping the suture around a top hook and a bottom hook. The two ends of the suture were tied using a Duncan loop sliding knot (configuration - DL=S//xS//xS) described in a study on "Optimizing Arthroscopic Knots" by Loutzenheiser, Harryman, Yung, France, and Sidles (1995). The DL=S//xS//xS configuration showed fewer differences in loop displacement and holding capacity compared to other surgical tied knots. Table 6 shows an average USP #2 suture pull strength of 40.3 lb and a standard deviation of 1.99 lb.

Table 6. Suture Pull Strength.

Test	Suture Type	Peak Load (lb)
1	USP #2	39.84
2	USP #2	40.92
3	USP #2	41.45
4	USP #2	40.38
5	USP #2	36.40
6	USP #2	42.00
7	USP #2	42.56
8	USP #2	38.73
Average Peak Load		40.3
Standard deviation		1.99

4.1.2 Effect of Hole Size in Acrylic Plate on Pull Strength

Figure 17 shows the average pull strength for cylinder shaped toggle type suture anchors in acrylic plate. The small anchors type A and B show a very similar pull strength trend. As the hole size is increased from 2.1 to 2.4 mm, the pull strength increased. At a 2.4 mm hole size, small anchor type A peaked at 31.6 lb and type B peaked at 31.5 lb. The pull strength decreased between 2.5 and 2.6 mm hole sizes for both anchors. The trend suggests that the small type anchors behave similarly since their external dimensions are identical (see Table 5), with the exception of type A anchor having a hole running from one end of the cylinder to the other like a pipe.

Large anchor type A and B showed a different pull strength trend. Type A reached a peak of 35.1 lb at a 3.4 mm hole. It decreased in strength at a 3.5 mm hole and then increased for 3.6 and 3.7 mm holes. The pull strengths did not surpass the peak strength obtained at the 3.4 mm hole size.

Type B had a trend similar to the small type anchors. The pull strength increased while the hole diameter increased from 3.3 to 3.5 mm where the anchor peaked at 36.0 lb. The pull strength decreased at 3.6 and 3.7 mm hole sizes. It is noted that large type A anchor has suture hole diameters of 0.889 mm whereas type B has diameters of 1.17 mm.

Figure 18 shows the standard deviation of pull strength for cylinder shaped toggle type suture anchors in acrylic plate. The standard deviation was identical at the hole size of 2.3 mm with a low value of 1.26 lb for both small type A and B anchors. Overall, deviations in small type B anchors were consistent falling into the range of 1.18 to 1.40 lb. Type A was less inconsistent with standard deviations ranging from 1.26 to 3.46 lb.

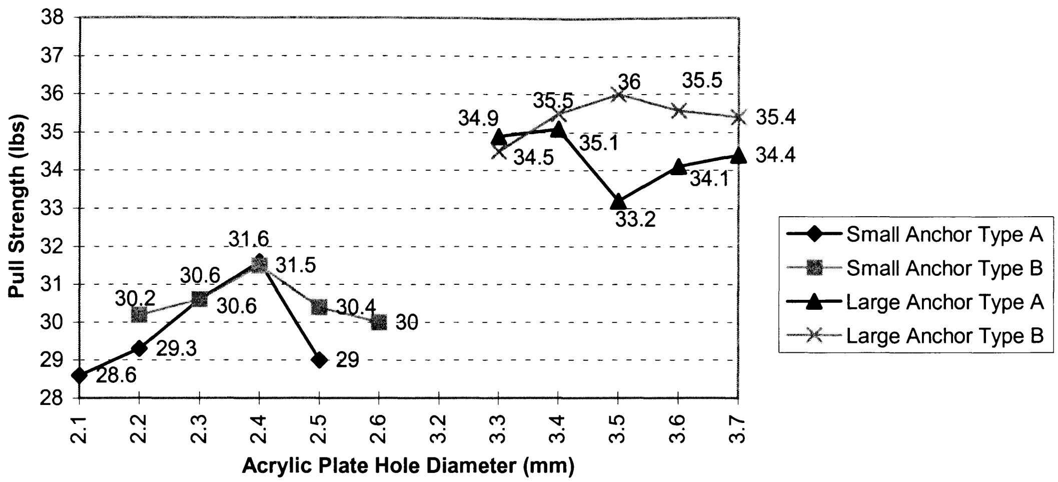

Figure 17. Average pull strength for cylinder shaped toggle type suture anchors in acrylic plate.

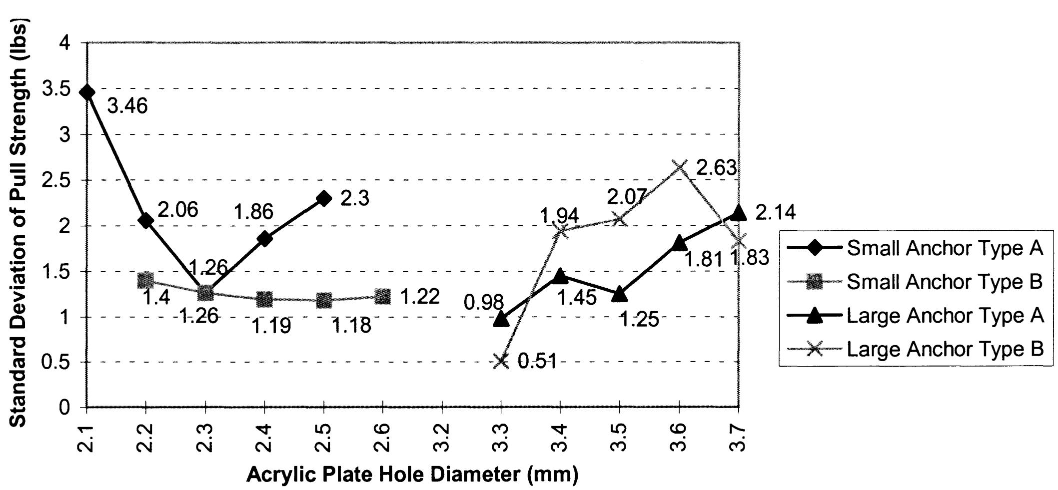

Figure 18. Standard deviation of pull strength for cylinder shaped toggle type suture anchors in acrylic plate.

The standard deviation of pull strength for the large anchors as a function of hole size was shown in Figure 18 as well. For both types A and B, the standard deviations increased generally with increasing the hole size. Type A had a range of standard deviation from 0.98 to 2.14 lb, whereas type B ranged from 0.51 to 2.63 lb.

For the small anchors, a hole size of 2.4 mm holds the highest strength for both types A and B displaying strengths of 31.6 and 31.5 lb with standard deviations of 1.86 and 1.19 lb, respectively. However, considering the fact that a 2.5 mm hole diameter showed decrease in pull strength, a hole size of 2.3 mm is more justified for both anchors for reliable performance of the suture anchor system. Both anchors had reasonable pull strengths of 30.6 lb and relatively low standard deviations of 1.26 lb at a hole diameter of 2.3 mm.

For the large anchors, a hole diameter of 3.4 mm held the most strength for type A and 3.5 mm held the most strength for type B. Nonetheless, a 3.5 mm showed a decrease in pull strength for large type A anchor. A hole diameter of 3.3 mm would be the most desirable with creditable pull strengths and somewhat low standard deviations for both anchors as shown in Figures 17 and 18.

4.1.3 Effect of Hole Size in Pig Bone on Pull Strength

The average pull strength for cylinder shaped toggle type B suture anchors in pig bone is shown in Figure 19 as a function of hole diameter. Small anchor type B demonstrated an increasing pull strength as the hole size was enlarged from 2.2 to 2.4 mm. Nonetheless, increasing the hole size to 2.5 mm proved to be dangerous since the small type B anchor failed upon toggle for all five anchors.

The pull strength of large anchor type B increased when the hole sizes were increased from 3.2 to 3.3 mm. At 3.4 and 3.5 mm, the pull strength began to decrease. The anchor held an impressive pull strength of 38.1 lb at a hole size of 3.3 mm. Large anchor type B with a hole size of 3.3 mm in pig bone is the only anchor that reflected a comparable pull strength of USP #2 suture.

Figure 20 displays the standard deviation of pull strength for type B suture anchors in pig bone. The small anchor showed a downward trend as the hole size increased from 2.2 to 2.4 mm. The standard deviation decreased from 5.04 to 3.43 lb as the pull strength reached a high of 32.2 lb. Even though 2.4 mm held the highest strength, it is too close to the 2.5 mm hole with all anchors failing upon toggle. Thus, a hole diameter of 2.3 mm would be recommended for the small anchors.

The large anchor had a standard deviation of 2.4 lb at a hole of 3.3 mm. The standard deviation went from 6.54 lb at a 3.2 mm hole size to 2.07 lb with a 3.4 mm hole. At 3.5 mm, the standard deviation increased to 5.93 lb again. A confidence level of 99.21% showed that the hole diameter in pig bone significantly affected the pull strength of large B anchors. As shown in Figures 19 and 20, a 3.3 mm hole proved to be the most desirable selection for the large B anchor in pig bone testing. It held the highest strength and resulted in a low standard deviation.

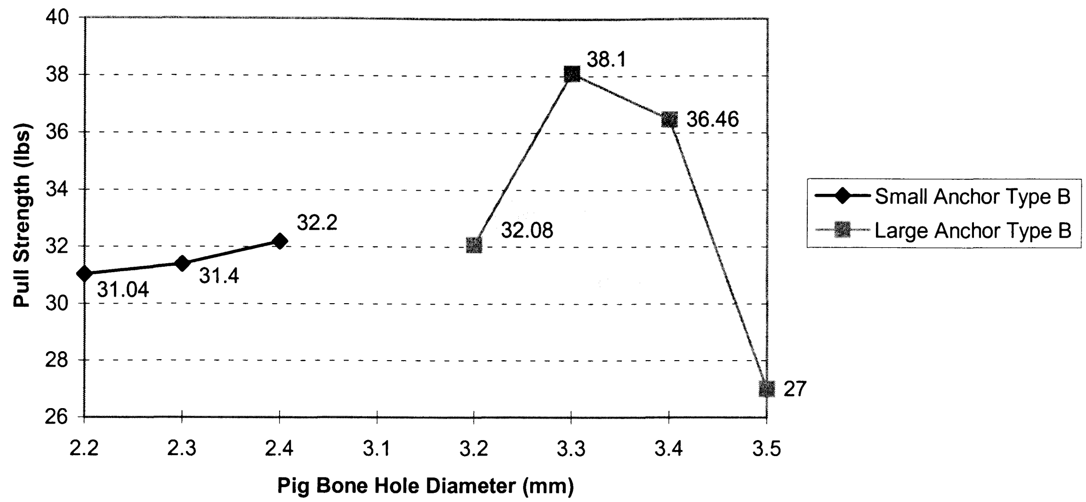

Figure 19. Average pull strength for cylinder shaped toggle type B suture anchors in pig bone.

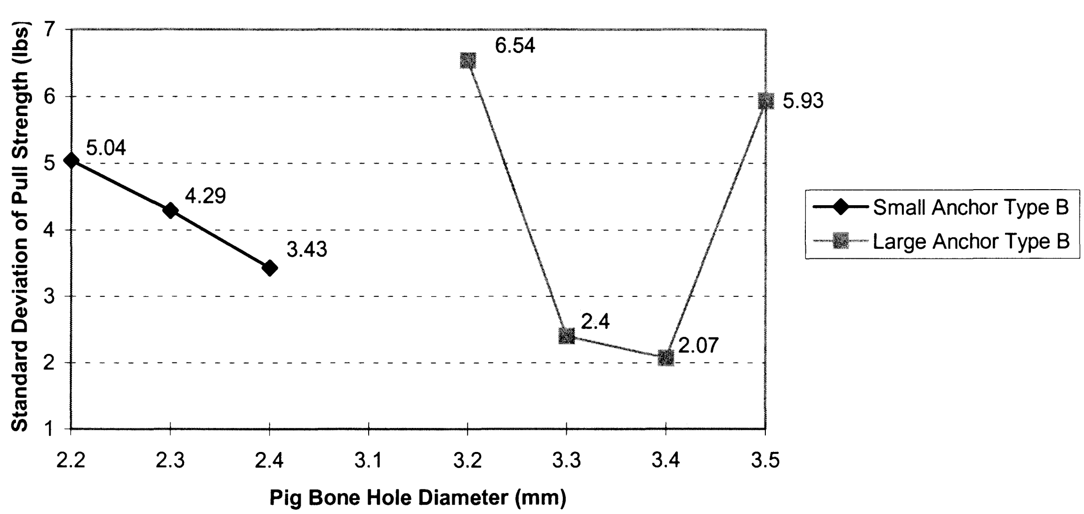

Figure 20. Standard deviation of pull strength for cylinder shaped toggle type B suture anchors in pig bone.

4.2 Mode of Failure for the Suture Anchor System

Figure 21 illustrates testing setup for the suture anchor system using USP #2 suture. Table 7 lists mode of failures for the cylinder shaped toggle type anchors, including testing model, failure location, the number of failures at location, the failure location percentage, and the average pull strength. For example, for small anchor type A, a total of 42 tests were performed with the acrylic plate model. Two failures occurred at the knot, 39 at the anchor, and one at the suture other than the knot or anchor. In other words, small anchor type A failed 92.8% at the anchor, 4.8% at the knot, and 2.4% at the suture. The average pull strength is 30.1 lb at the anchor and 31.0 lb at the knot, respectively. Average pull strength at the suture was 21.5 lb, breaking at a frayed area caused by insertion. The high percentage of failures at the anchor suggests that the anchor caused damages on the suture.

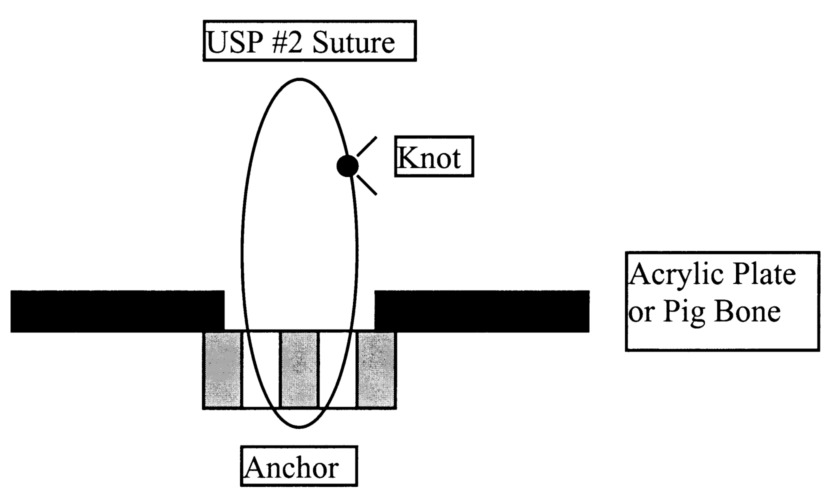

Figure 21. Diagram of testing setup for USP #2 suture/anchor system.

Table 7. Mode of Failure for Cylinder Shaped Toggle Type Suture Anchors.

Anchor Type	Model	Failure Location	Number of Failure at Location	Percent (%)	Average Strength (lb)
Small Anchor A	Acrylic Plate	Suture	1/42	2.4	21.5
Small Anchor A	Acrylic Plate	Knot	2/42	4.8	31.0
Small Anchor A	Acrylic Plate	Anchor	39/42	92.8	30.1
Small Anchor B	Acrylic Plate	Knot	1/40	2.5	28.4
Small Anchor B	Acrylic Plate	Anchor	39/40	97.5	30.6
Small Anchor B	Pig Bone	Knot	4/15	26.67	32.0
Small Anchor B	Pig Bone	Anchor	8/15	53.33	33.9
Small Anchor B	Pig Bone	Pullout	3/15	20.0	24.8
Large Anchor A	Acrylic Plate	Knot	16/40	40.0	34.7
Large Anchor A	Acrylic Plate	Anchor	24/40	60.0	34.1
Large Anchor B	Acrylic Plate	Knot	25/40	62.5	34.6
Large Anchor B	Acrylic Plate	Anchor	15/40	37.5	36.7
Large Anchor B	Pig Bone	Knot	13/20	65.0	36.0
Large Anchor B	Pig Bone	Anchor	3/20	15.0	36.9
Large Anchor B	Pig Bone	Pullout	4/20	20.0	22.5

Small anchor type B failed 97.5% at the anchor and 2.5% at the knot when tested using the acrylic plate model. It reached average pull strengths of 30.6 lb when failed at the anchor and 28.4 lb for failures at the knot. In the pig bone testing model, 53.3% of small anchor type B failed at the anchor, 26.67% at the knot, and 20% by anchor pullout. The average pull strength was 33.9 lb at the anchor, 32.0 lb at the knot, and 24.8 lb when the anchor was pulled out.

Small anchor type A and B failed primarily at the anchor for both acrylic and pig bone models. From the pull strength testing results under the previous sections, it is known that the small anchors reach a peak load around 32.0 lb in the acrylic plate and the pig bone models using a 2.4 mm hole size. However, USP #2 suture has an average pull strength of 40.3 lb. It is clear that the small anchor design limited the suture anchor system from reaching its potential strength.

Sixty percent of large anchors type A failed at the anchor and 40% at the knot during acrylic plate testing. It is important to note that small type A and B anchors and large type A anchors have suture hole sizes of 0.889 mm. As a result, large type A anchor demonstrated characteristics similar to the smaller anchors. The anchor designs caused the suture to fail primarily at the anchor. Large A anchors reached a peak load of 35.1 lb in acrylic testing which was also lower than the USP #2 suture strength of 40.3 lb.

For large Type B anchors, only 37.5% of the tests failed at the anchor and 62.5% at the knot for the acrylic plate model. The average pull strengths were 34.6 lb for the knot and 36.7 lb for the anchor. During pig bone testing, large anchor B had 15% of its tests fail at the anchor, 65% at the knot, and 20% by anchor pullout. The average pull strength for the anchor was 36.9 lb at the anchor, 36.0 lb at the knot, and 22.5 lb when the anchor was pulled out.

Large anchor type B failed predominantly at the knot. It was also the only anchor to peak at 38.1 lb at a hole size of 3.3 mm during pig bone model testing. Large anchor B demonstrated a pull strength and standard deviation closer to that of USP #2 suture. Large anchor type B has suture hole sizes of 1.17 mm, which is the only difference from the large type A design. The suture hole size of 1.17 mm improved the anchor performance by shifting the failure location away from the anchor to the knot.

4.3 SEM Analysis Results

Figure 22 depicts the micrographs of scanning electron microscopy (SEM) for interaction between USP #2 suture and small type A anchor as tension on the suture was increased. The tension was applied gradually to the suture/anchor system using a tensile stage with a control outside the vacuum chamber. The SEM analysis was performed at variable pressure mode, thus, the polymeric suture was observed as it was stretched, without any coating. Figure 22 (a) shows the initial position in which no tension was applied to the suture/anchor system. Figure 22 (b) illustrates the suture/anchor interaction with a tension of 2.0 lb. The split screen shows more details of a single strand appearing to be separated.

Figure 22 (c) demonstrates the suture/anchor system subject to a tension of 8.0 lb. At this tension level, a visible strand breakage was developed near the lower suture hole. The split screen shows more details on the suture fracture. Figure 22 (d) indicates that as the tension was increased to 9.0 lb, more suture strands started breaking. When the suture tension was increased to 10.0 lb as shown in Figure 22 (e), significant fracture was observed on many strands. Figure 22 (f) presents a more detailed view of suture strand fractures occurring near the lower suture hole in the anchor.

Figure 22 (g) shows the suture/anchor system as the tension was applied up to 11.0 lb before complete failure at the anchor. Figure 22 (h) illustrates more details of the suture breakage near the anchor hole. It is noted from this series of observations that the suture/anchor system failed at the suture hole in the anchor by suture laceration. The rim of the anchor hole caused shearing on the suture when tension load was increasingly applied. This study is consistent with results of previous experimental observation on failure mode for this suture/anchor system where 92.8% of failure occurred at the anchor.

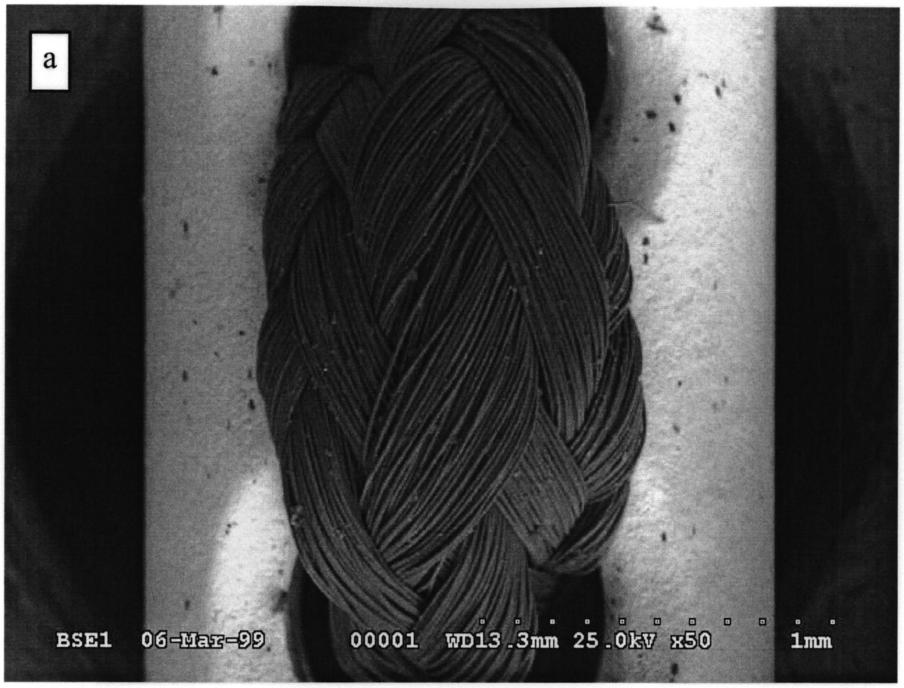

Figure 22 (a). Small type A anchor with USP #2 suture without tension.

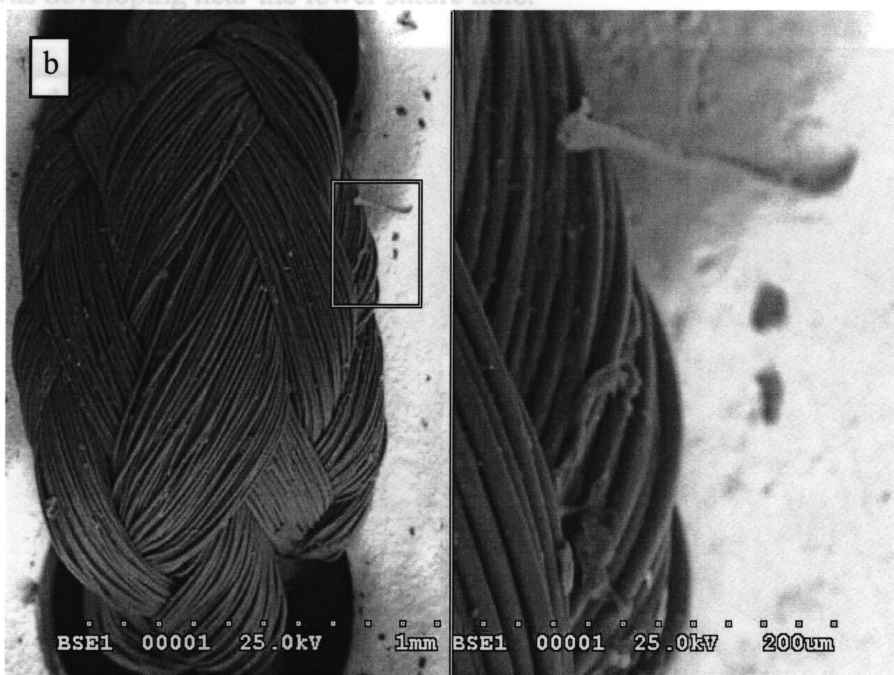

Figure 22 (b). Small type A anchor with USP #2 suture in tension of 2.0 lb. A single suture strand appeared to be separated.

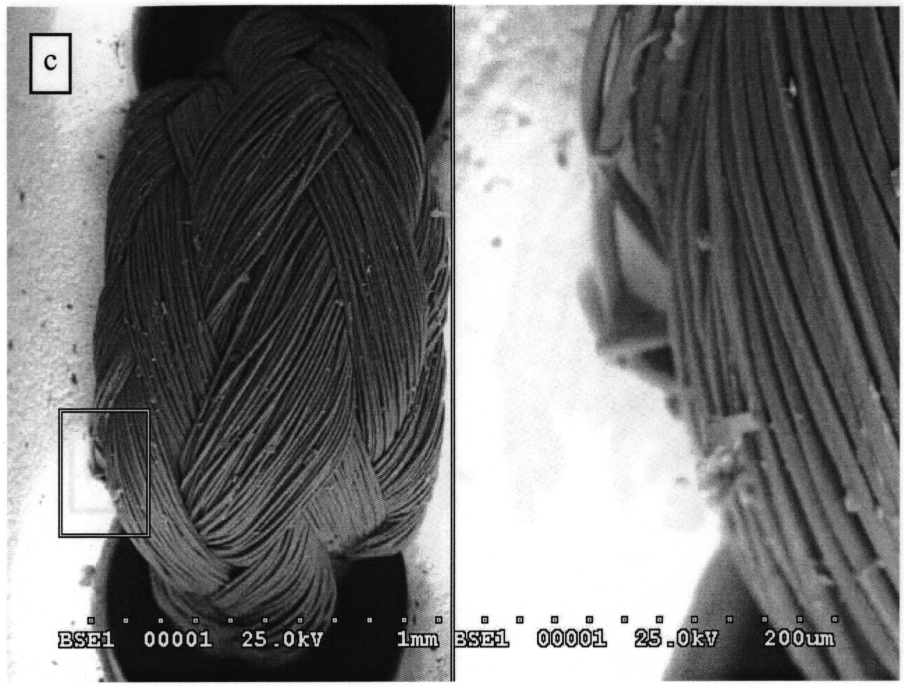

Figure 22 (c). Small type A anchor with USP #2 suture in tension at 8.0 lb. Suture fracture was developing near the lower suture hole.

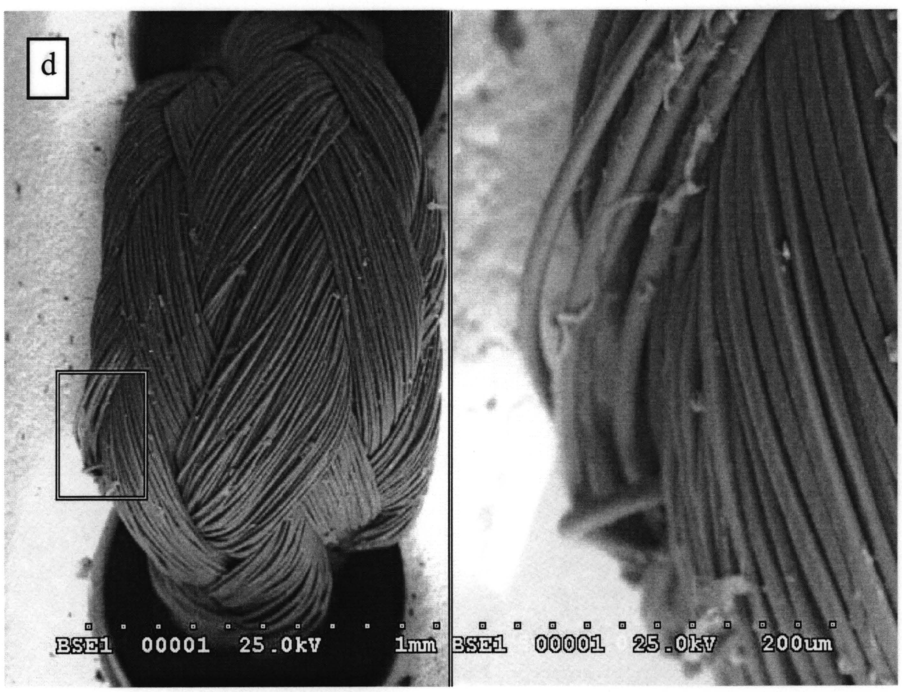

Figure 22 (d). Small type A anchor with USP #2 suture in tension at 9.0 lb. Suture fracture progressed as the tension was increased.

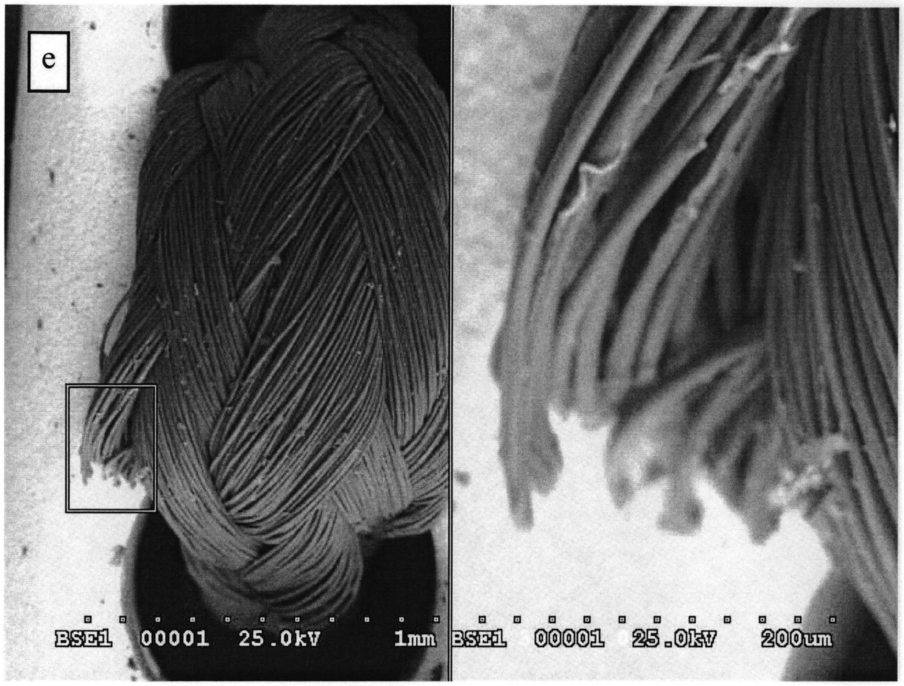

Figure 22 (e). Small type A anchor with USP #2 suture in tension at 10.0 lb showing noticeable suture fracture.

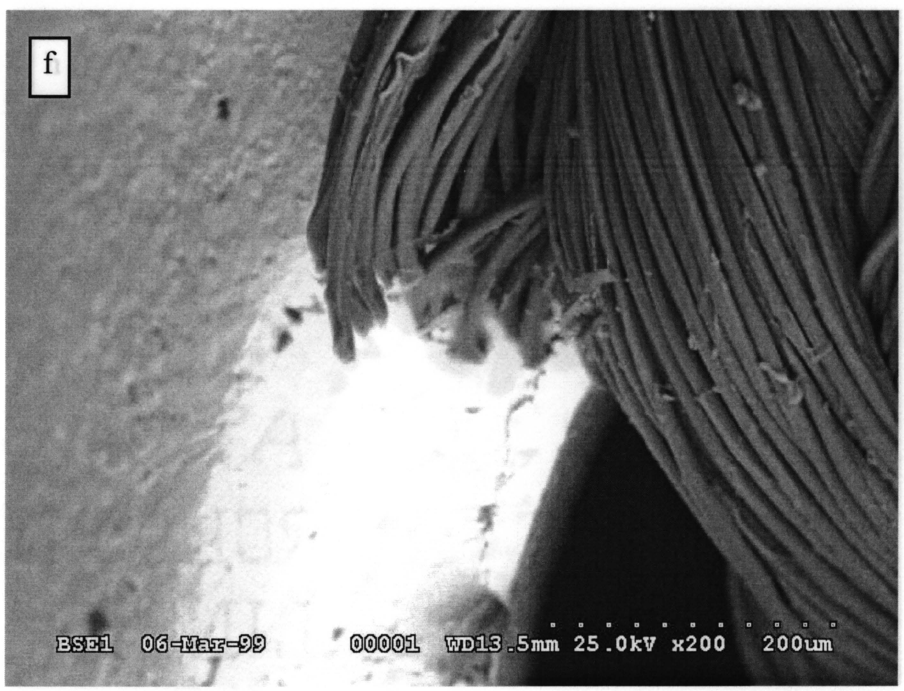

Figure 22 (f). Suture fracture in tension at 10.0 lb at a magnification of 200 times.

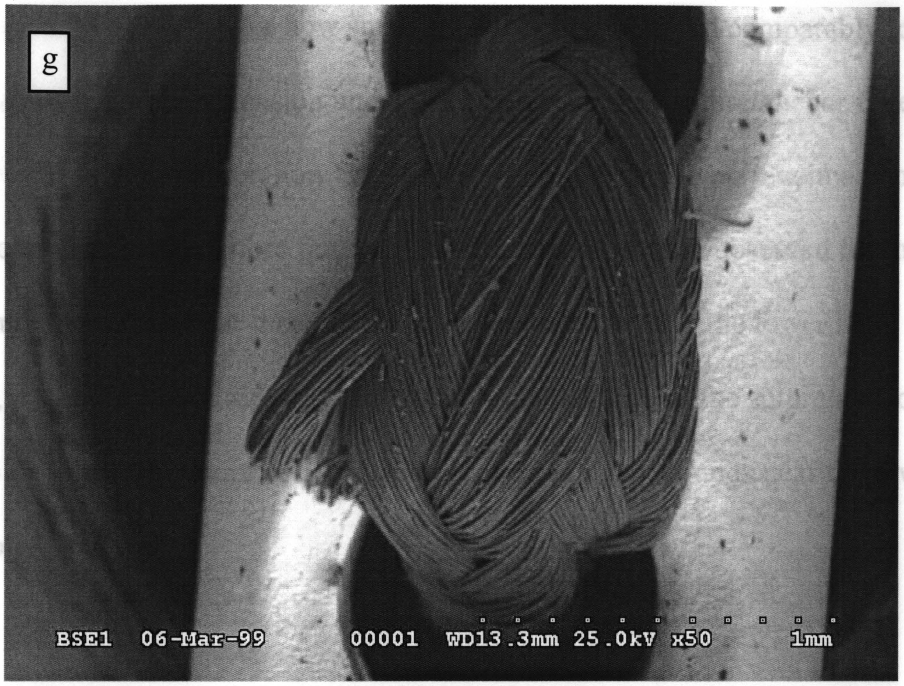

Figure 22 (g). Small type A anchor with USP #2 suture in tension at 11.0 lb before failing at the fractured area near the anchor hole.

Figure 22 (h). Fracture location before failure at a magnification of 200 times.

Figure 23 demonstrates how small anchor type B behaved comparably to small type A anchor at 11.0 lb of tension under SEM analysis. The suture/anchor failed near the lower hole by suture laceration. Figure 23 (a) provides an overview image of the suture/anchor interaction before failure. Two fracture sites were observed for the system. One fracture took place near the upper hole while the other near the lower hole. However, it was the lower rupture that led to ultimate failure of the suture/anchor system. Figure 23 (b) illustrates more details on the fracture of many strands near the lower anchor hole.

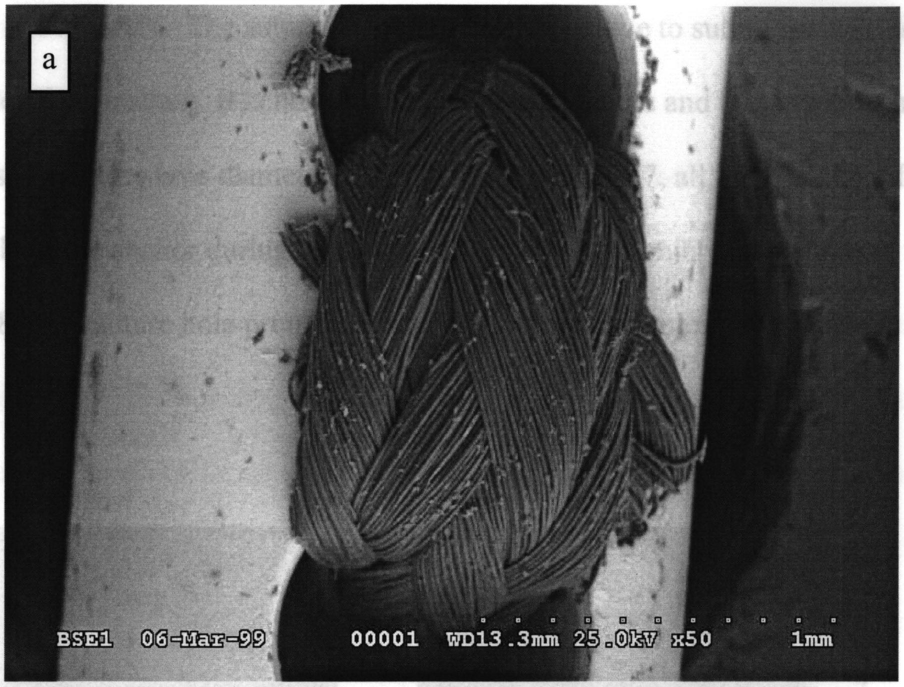

Figure 23 (a). Small type B anchor with USP #2 suture in tension at 11.0 lb before failing.

Figure 23 (b). Failure location at a magnification of 200 times.

Large anchor A demonstrated characteristics similar to the smaller type anchors, as shown in Figure 24. The suture/anchor system failed due to suture fracture near the lower hole of the anchor. It is noticed that the small anchors and large type A anchor have the same suture hole diameter of 0.889 mm. In Table 7, all three anchors failed extensively at the anchor during tension tests. The electron microscope images reveal that a 0.889 mm suture hole promoted suture failures at the holes under applied load.

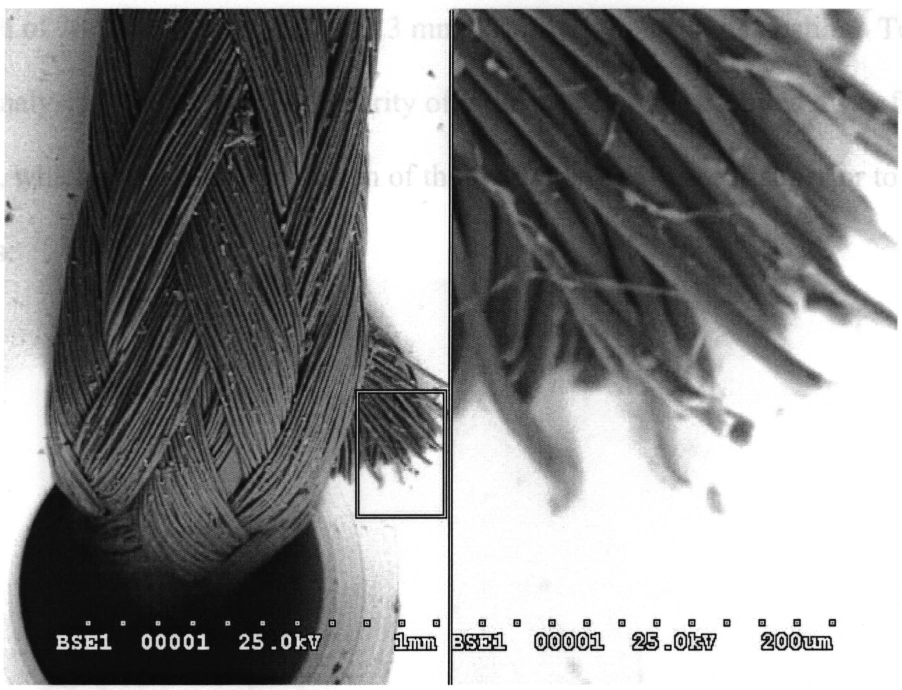

Figure 24. Large type A anchor with USP #2 suture in tension at 11.5 lb before failing at the fractured area.

Figure 25 shows the suture/anchor system with large type B anchor failing at 11.0 lb of tension. Figure 25 (a) is the view near the upper hole whereas Figure 25 (b) is the view near the lower hole. Failure occurred where the tensile stage secured the suture, instead of at the anchor. Large B was the only anchor that had a failure location other than the hole at the anchor.

The larger hole diameter in the anchor seemed to shift the failure location away from the anchor. The fact suggests that the hole is large enough to accommodate suture under applied load. The larger suture hole allows the anchor to reach its maximum peak strength of 38.1 lb at a hole size of 3.3 mm during pig bone model testing. Testing and SEM analysis indicate that the majority of large type B anchors failed away from the anchor, which proves that the design of the type B large anchor is superior to other designs.

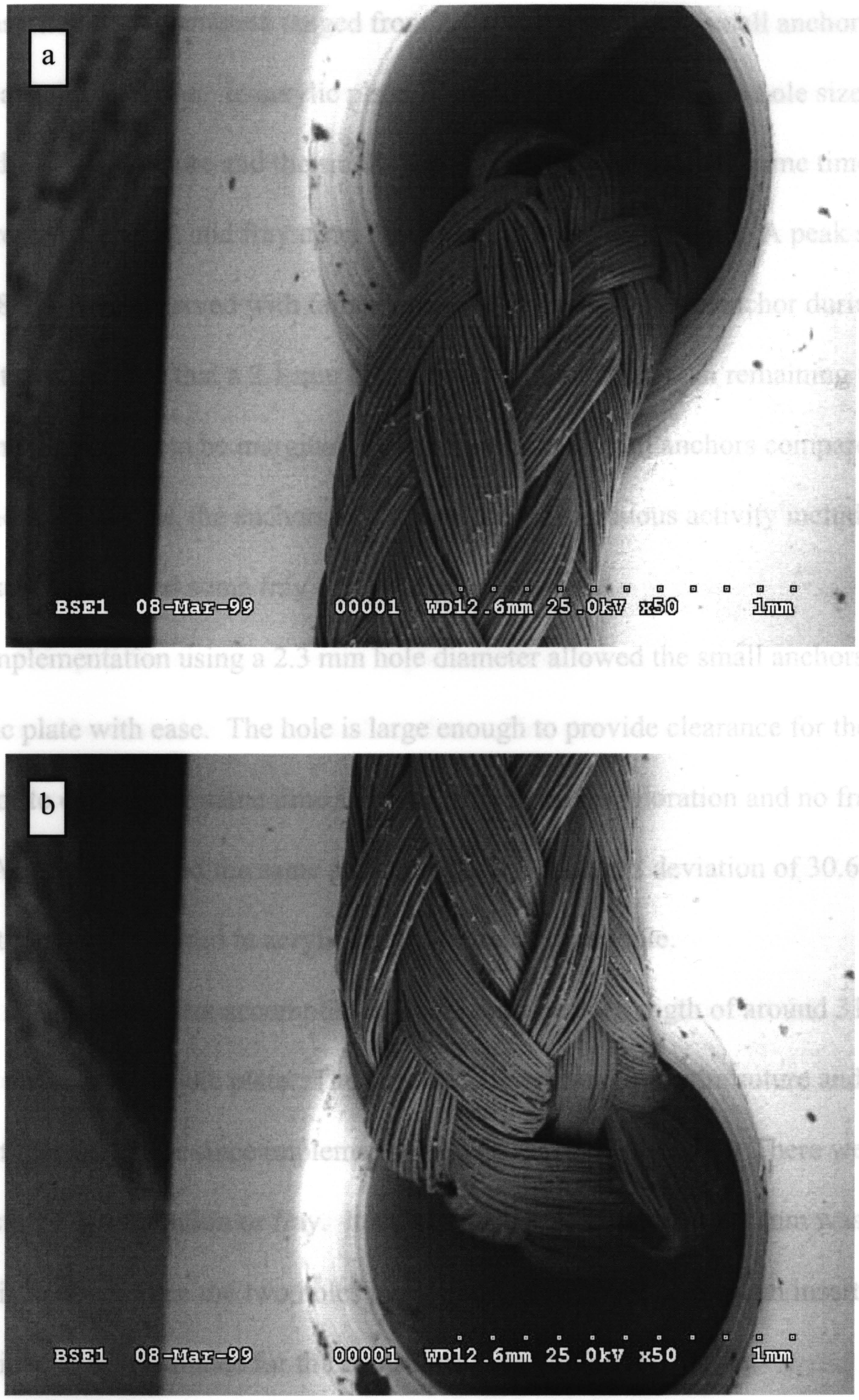

Figure 25. Large type B anchor with USP #2 suture after failing at 11.0 lb. Failure occurred where the tensile stage secured the suture, not at the anchor. (a) Upper hole and (b) Lower hole.

4.4 Observation on Implementation

Insertion hole diameters ranged from 2.1 to 2.6 mm for the small anchors in acrylic plate and pig bone. In acrylic plate, it was found that a 2.1 mm hole size was too tight for the USP #2 suture and the small type A anchor to enter at the same time. There was suture discoloration and fray upon forceful insertion into the hole. A peak strength of only 28.7 lb was observed with failure occurring primarily at the anchor during testing. It was decided that a 2.1 mm hole size would not be used in remaining testing. A 2.2 mm hole proved to be marginal for insertion of the small anchors compared to the 2.1 mm hole. However, the anchors still demonstrated strenuous activity including suture discoloration and some fray during implementation.

Implementation using a 2.3 mm hole diameter allowed the small anchors to enter the acrylic plate with ease. The hole is large enough to provide clearance for the suture and anchor to enter at the same time showing little to no discoloration and no fray. Small anchors A and B achieved the same pull strength and standard deviation of 30.6 and 1.26 lb respectively, when tested in acrylic plate using a 2.3 mm hole.

A 2.4 mm hole size accomplished the highest peak strength of around 31.5 lb for the small anchors in acrylic plate. The hole was large enough for the suture and anchor to enter at the same time since implementation was carried out easily. There were no signs of suture discoloration or fray. It should further be noted that 2.4 mm was the outside distance between the two holes in the small anchors. The 2.4 mm insertion hole size provided exact clearance for the two suture holes following toggle.

Increasing the hole size to 2.5 and 2.6 mm showed decrease in pull strength for small anchors A and B in acrylic plate even though implementation was completed easily. The larger diameters provided the small anchors with excess clearance. Consequently, anchor stability was affected and resulted in lower pull strengths.

In pig bone testing, 2.2 mm was the smallest diameter used for small type B anchors since anchor insertion was difficult at times while others it was fair. Implementation using a 2.3 mm hole was carried out with ease showing no signs of suture discoloration or fray. Small B anchor held its highest peak strength of 32.2 lb at a hole diameter of 2.4 mm. Increasing the hole diameter to 2.5 mm proved detrimental for small type B anchor in pig bone. The anchors went into the hole with ease, but no pull test could be performed since all anchors failed upon toggle. A hole of 2.5 mm allowed excess clearance making anchor implementation and testing unstable.

Based upon the observations on implementation, a hole diameter between 2.3 and 2.4 mm would be desirable for the small anchors. Yet, the 2.4 mm hole was too close to the 2.5 mm hole in which all anchors failed upon toggle. It is recommended that a hole size of 2.3 mm be used because of easy implementation, consistently high pull strengths and relatively low standard deviations of pull strengths.

Insertion hole diameters for large anchors ranged from 3.2 to 3.7 mm for the acrylic plate and bone models. In acrylic plate, 3.2 mm was undesirable since the large anchors and suture had to be physically forced into the hole. No pull tests were performed as a result. A 3.3 mm hole was the smallest hole tested in the acrylic plate model. The hole seemed tight for the suture and large anchors to enter at the same time, attributing to suture discoloration and fray during implementation. Hole sizes ranging from 3.4 to 3.7 mm were evaluated for the large anchors A and B in acrylic plate. Insertion became easier as the hole size increased, but pull strength decreased as a result.

In pig bone, 3.2 mm was the smallest hole tested utilizing a large type B anchor. It was found that the anchor was somewhat difficult to insert for the majority of the tests. Insertion at a 3.3 mm hole improved slightly compared with 3.2 mm. Nonetheless, the 3.3 mm hole size obtained the highest peak load of 38.10 lb and a standard deviation of 2.4 lb which is close to the pull strength of 40.3 lb and standard deviation of 1.99 lb for a USP #2 suture. SEM analysis uncovered that the design of large B anchor allowed the suture/anchor system to achieve a maximum strength since it failed away from the anchor.

The pull strength decreased at a hole diameter of 3.4 mm. It continued to decrease to a very low pull strength of 27.0 lb at 3.5 mm making it the final hole diameter evaluated for large type B anchor in pig bone. Three out of five anchors failed with the anchor pulling out and two tests failed at the knot. This shows that the hole is too big for the security of the suture/anchor system.

Given the observations on implementation and pull strength, it seems that a hole size of 3.3 and 3.4 mm would be beneficial for the large type B anchor. Both holes exhibited similar characteristics upon insertion. It is recommended that a 3.3 mm insertion hole be used because of its high pull strength, low standard deviation, and relatively modest implementation.

CHAPTER 5

Summary, Conclusions, and Recommendations for Further Research

5.1 Summary

Variable pressure SEM study showed that small type A and B and large type A anchors failed at the anchor. This research revealed that suture holes of 0.889 mm in small types A and B and large type A anchors do not seem to provide enough clearance for the USP #2 suture under load. For large type B anchors, SEM exposed that the majority of failures occurred away from the anchor. This fact suggests that suture holes of 1.17 mm in the anchor seem to be large enough to provide sufficient pull strength for the suture/anchor system.

From pull strength testing and an implementation point of view, a 2.3 mm insertion hole size had the most favorable results for the small type anchors in acrylic plate and pig bone. Implementation using a 2.3 mm insertion hole allowed the anchor and suture to enter both models with ease. Pull strength results showed that a hole diameter of 3.3 mm would provide an optimum pull strength for large type B anchors. Large type B anchors achieved a strength comparable to that of USP #2 suture at this insertion hole size.

5.2 Conclusions

The following conclusions were made from the study of the optimization of insertion holes and anchor design for cylinder shaped toggle type suture anchors.

(1) Variable pressure SEM study showed that small type A and B and large type A anchors failed at the anchor. The large type B anchors failed away from the anchor.

(2) For small types A and B and large type A anchors, suture holes of 0.889 mm in the anchors do not seem to provide enough clearance for the USP #2 suture under load. As a result, suture hole design modification should be considered to optimize the potential strength of the suture/anchor system.

(3) For large type B anchors, the majority of failures occurred away from the anchor. This fact suggests that suture holes of 1.17 mm in the anchor seem to be large enough to provide sufficient pull strength for the suture/anchor system.

(4) From an implementation point of view, a 2.3 mm insertion hole size would be the best choice for small type A and B anchors. Implementation using a 2.3 mm insertion hole allowed the anchor and suture to enter the models with ease. A hole size of 2.5 mm proved detrimental during small anchor type B in pig bone testing. A 2.4 mm hole size held the highest strength during acrylic plate and pig bone testing but it is too close to the 2.5 mm hole.

(5) For large type B anchors, ANOVA indicates that the hole diameter significantly affected the pull strength of the suture/anchor system in pig bone. The results showed that a hole diameter of 3.3 mm would provide an optimum pull strength for large type B anchors.

5.3 Recommendations for Further Research

The following recommendations for further research were made in regard to this study.

(1) Suture hole design change similar to large type B anchors for small type A and B anchors and large type A anchors so that a pull strength comparable to USP #2 suture can be obtained.

(2) Research on machining processes to improve suture holes in small type A and B anchors and large type A anchors to reach higher pull strengths. The existing holes seem to shear the suture strands.

(3) Research to determine the minimum load needed for surgical repair of the various bone regions using a suture anchor. For example, what would be the minimum load that a suture anchor/suture should hold when repairing a torn rotator cuff. This would determine if the pull strengths obtained by small type A and B anchors and large type A anchors were sufficient.

(4) For small type A and B anchors and large type A anchors, using a suture with a diameter half the size of the 0.889 mm suture hole. USP #2 has a diameter between 0.5 to 0.59 mm and large type B anchor has a suture hole diameter of 1.17 mm, which allows enough clearance for two sutures.

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Appendixes

Testing Results for Small Anchor Type A in Acrylic Plate

Diameter of hole (mm)	Number of tests performed	Average pull strength in pounds	Standard deviation in pounds
2.1	8	28.7	3.46
2.2	8	29.3	2.06
2.3	8	30.6	1.26
2.4	10	31.6	1.86
2.5	8	29.0	2.30

Overview

From the results, the pull strength increases, while the hole size increases. This applies for the hole sizes between 2.1 mm and 2.4 mm. The strength finally dropped when the hole size of 2.5 mm was used for testing. The drop in strength provided a stopping point for the Acrylic plate testing. In this summary, *discoloration* means that the suture changed color in an area where it was pinched. *Fray* means that the some of the strands in the suture actually broke during injection - caused by pinching.

2.1 mm hole size

For the eight tests, eight different anchors were used. There was discoloration upon insertion into the sample hole piece. The suture frayed upon injection into the hole because the hole seemed too tight for the suture and the anchor to enter at the same time. On test number 5, the suture did break at the frayed area. 1 of 8 tests or 12.5% of the anchors broke at the frayed area. 7 of 8 tests or 87.5% failed at the anchor.

2.2 mm Hole Size

The 2.2 mm hole size is the hole presently being used by surgeons. As the anchor was inserted, discoloration occurred because the induction device was pinching the suture between its outer tube and the plastic piece. Although the suture appeared to fray at the discoloration area, it broke primarily at the anchor. 8 of 8 tests or 100% failed at the anchor.

2.3 mm Hole Size

For the 2.3 mm hole size, the anchor went into the hole with ease. There was little to no discoloration with no fray upon insertion. The larger hole allows the necessary clearance for implementation. 8 of 8 tests or 100% failed at the anchor.

2.4 mm Hole Size

Ten tests were ran for the hole size of 2.4 mm because the PK load results were very low for tests 7 and 8. It was desired to see if the PK load would increase after a few more tests-which it did. There was little to no discoloration upon insertion and the anchor went into the hole with ease. The highest peak load of 31.6 pounds was obtained at this hole size. 1 of 10 tests or 10% failed at the knot. 9 of 10 tests or 90% failed at the anchor.

2.5 mm Hole Size

For 2.5 mm hole size, the anchor went into the hole with ease. The average load went down from the previous hole size strength's. This is a significant decrease compared to the other hole sizes. It was concluded that the testing of various hole sizes is now complete considering the fact that the strength hit its peak at the 2.4 mm hole size and then went back down at the 2.5 mm hole size. 1 of 8 tests or 12.5% failed at the knot. 7 of 8 tests or 87.5% failed at the anchor.

Testing Results for Small Anchor Type B in Acrylic Plate

Small anchor type B does not have the hollowed out center hole which is in the small anchor type A design (only difference).

Diameter of hole (mm)	Number of tests performed	Average pull strength in pounds	Standard deviation in pounds
2.2	8	30.2	1.40
2.3	8	30.6	1.26
2.4	8	31.5	1.19
2.5	8	30.4	1.18
2.6	8	30.0	1.22

Overview

From the results, the pull strength increases, while the hole size increases. This applies for the hole sizes between 2.2 mm and 2.4 mm. The strength finally dropped when the holes size of 2.5 mm and 2.6 mm were used for testing. The drop in strength provided a stopping point for the Acrylic plate testing. In this summary, *discoloration* means that the suture changed color in an area where it was pinched. *Fray* means that the some of the strands in the suture actually broke during injection - caused by pinching.

2.2 mm hole size

The 2.2 mm hole size is the hole presently being used by surgeons. Eight different anchors were used for the eight tests. There was little discoloration upon insertion into the sample hole piece. The hole seemed tight for the suture and the anchor during tests 5 and 7. For the most part, The anchor and suture were able to fit into the insertion hole size of 2.2 mm. 8 of 8 tests or 100% failed at the anchor.

2.3 mm Hole Size

For the 2.3 mm hole size, the anchor went into the hole with ease. There was little discoloration upon insertion. The bigger hole is allowing more clearance for the suture and the anchor to enter at the same time. 8 of 8 tests or 100% failed at the anchor.

2.4 mm Hole Size

Eight tests were ran for the hole size of 2.4 mm. There was little to no discoloration upon insertion into the sample piece, which cause the anchor to go into the hole with ease. The 2.4 mm hole size obtained the highest peak load of 31.5 pounds with a small standard deviation 1.19 pounds. 8 of 8 tests or 100% failed at the anchor.

2.5 mm Hole Size

For 2.5 mm hole size, the anchor went into the hole with ease. The suture broke at the anchor for the most part with exception of one breaking at the knot (test 4). The average load went down from the previous hole size strength's. 1 of 8 tests or 12.5% failed at the knot. 7 of 8 tests or 87.5% failed at the anchor.

2.6 mm Hole Size

For the 2.6 mm hole size, there was no discoloration upon insertion. The anchor went into the hole with ease. It was concluded that the testing of various hole sizes is now complete considering the fact that the strength hit its peak at the 2.4mm hole size and then went back down at the 2.5 mm and 2.6 mm hole sizes. 8 of 8 tests or 100% failed at the anchor.

Testing Results for Small Anchor Type B in Pig Bone

Diameter of hole (mm)	Number of tests performed	Average pull strength in pounds	Standard deviation in pounds
2.2	5	31.04	5.04
2.3	5	31.40	4.29
2.4	5	32.20	3.43
2.5	5	failed at toggle	failed at toggle

Overview

From the results, the pull strength increases, while the hole size increases. This applies for the hole sizes between 2.2 mm and 2.4 mm. The anchors failed upon toggle for the hole size of 2.5 mm. In this summary, *discoloration* means that the suture changed color in an area where it was pinched. *Fray* means that the some of the strands in the suture actually broke during injection - caused by pinching.

2.2 mm hole size

The 2.2 mm hole size is the hole presently being used by surgeons. For the five tests, five different anchors were used. The hole seemed tight for the suture and the anchor. The suture broke at the anchor for test's 1 and 3, at the knot during test's 2 and 5, and by anchor pullout for test 4. 2 of 5 tests or 40% failed at the anchor, 2 of 5 tests or 40% at the knot, and 1 of 5 tests or 20% failed by anchor pullout.

2.3 mm Hole Size

For the 2.3 mm hole size, the anchor went into the hole with ease. The suture broke at the anchor for all of the successful tests. During test 4, the anchor failed by anchor pullout. 1of 5 tests or 20% failed by anchor pullout and 4 of 5 or 80% failed at the anchor.

2.4 mm Hole Size

The anchor went into the hole with ease. The suture broke at the anchor for test's 2 and 5, and at the knot for test's 3 and 4. The suture failed by anchor pullout for test 1. The 2.4 mm hole size obtained the highest peak load of 32.2 pounds with a small standard deviation of 3.43 pounds. 2 of 5 tests or 40% failed at the anchor, 2 of 5 tests or 40% at the knot, and 1 of 5 tests or 20% failed by anchor pullout.

2.5 mm Hole Size

For 2.5 mm hole size, the anchor went into the hole with ease. However, all tests failed upon toggle.

Testing Results for Large Anchor Type A in Acrylic Plate

Diameter of hole (mm)	Number of tests performed	Average pull strength in pounds	Standard deviation in pounds
3.3	8	34.90	0.98
3.4	8	35.10	1.45
3.5	8	33.20	1.25
3.6	8	34.10	1.81
3.7	8	34.40	2.14

Overview

From the results, the hole size of 3.4 mm holds the highest average pull out strength of 35.10 lbs. Yet, the larger anchor testing results are not consistent with the results for the smaller anchors. The smaller anchors testing showed a curve that went up and reached a high peak load and then the curve went straight back down. Large anchor type A results show a curve that varies (could go up or down) while hole size increases. In this summary, *discoloration* means that the suture changed color in an area where it was pinched. *Fray* means that the some of the strands in the suture actually broke during injection - caused by pinching.

3.3 mm hole size

Eight different anchors were used for the eight tests. There was discoloration upon insertion and the suture also frayed. The hole seemed a little tight for the suture and the anchor to enter at the same time. It was concluded that the 3.3 mm hole size will be the smallest hole size used in large anchor testing. 2 of 8 tests or 25% failed at the knot and 6 of 8 tests or 75% failed at the anchor.

3.4 mm Hole Size

The 3.4 mm hole size is the hole presently being used by surgeons. There was little discoloration upon insertion into the sample hole piece. The suture broke at the anchor only three times during test's 1, 2, and 7. The suture broke at the knot five times for test's 3, 4, 5, 6, and 8. The anchor peaked at a load of 35.1 pounds with a standard deviation of 1.45 pounds. 5 of 8 tests or 62.5% failed at the knot and 3 of 8 tests or 37.5% failed at the anchor.

3.5 mm Hole Size

There was no discoloration upon insertion into the sample hole piece. The suture broke at the anchor only three times during test's 2, 4, and 6. The suture broke at the knot five times for test's 1, 3, 5, 7, and 8. The pull strength began to decrease at this point. 5 of 8 tests or 62.5% failed at the knot and 3 of 8 tests or 37.5% failed at the anchor.

3.6 mm Hole Size

The anchor went into the hole with ease. The suture broke at the anchor for the most part (test 3 and 8, the suture broke at the knot). 2 of 8 tests or 25% failed at the knot and 6 of 8 tests or 75% failed at the anchor.

3.7 mm Hole Size

The anchor went into the hole with ease. The suture broke at the anchor for the most part (test 2 and 7, the suture broke at the knot). The pull strength did not increase greater than the value obtained by the 3.4 mm hole size, so testing is completed. 2 of 8 tests or 25% failed at the knot and 6 of 8 tests or 75% failed at the anchor.

Testing Results for Large Anchor Type B in Acrylic Plate

The large anchor type B has greater suture hole sizes than the large anchor type A. The type B hole sizes are 1.194 mm in diameter while the type A anchors have diameters of 0.889 mm.

Diameter of hole (mm)	Number of tests performed	Average pull strength in pounds	Standard deviation in pounds
3.3	8	34.54	0.51
3.4	8	35.47	1.94
3.5	8	36.00	2.07
3.6	8	35.56	2.63
3.7	8	35.36	1.83

Overview

From the results, the hole size of 3.5 mm holds the highest average pull out strength of 36.0 lbs. The results show a curve that went up and reached a high peak load and then the curve went straight back down. In this summary, *discoloration* means that the suture changed color in an area where it was pinched. *Fray* means that the some of the strands in the suture actually broke during injection - caused by pinching.

3.3 mm hole size

Eight different anchors were used for the eight tests. There was suture discoloration and fray upon insertion into the sample piece. The hole seemed tight to moderate for the suture and the anchor to enter at the same time. The suture primarily broke at the knot (with the exception of tests 6 and 7, the suture broke at the anchor) and not at the frayed area. 6 of 8 tests or 75% failed at the knot and 2 of 8 tests or 25% failed at the anchor.

3.4 mm Hole Size

The 3.4 mm hole size is the hole presently being used by surgeons. There was little discoloration upon insertion into the sample piece. The suture broke at the anchor only three times during test's 3,7, and 8 and at the knot for the rest of the tests. 5 of 8 tests or 62.5% failed at the knot and 3 of 8 tests or 37.5% failed at the anchor.

3.5 mm Hole Size

There was little to no discoloration upon insertion into the sample hole piece. The suture broke at the anchor only four times during test's 1,3,7, and 8. The suture broke at the knot for the rest of the tests. The average load hit its peak load of 36.0 pounds and a standard deviation of 2.07 pounds at this hole size. Large anchor type A hit its peak of 35.1 pounds at the hole size of 3.4 mm. 4 of 8 tests or 50% failed at the knot and 4 of 8 tests or 50% failed at the anchor.

3.6 mm Hole Size

The anchor went into the hole with ease. The suture broke at the knot for the most part with the exceptions of tests 3 and 6 at the anchor. The peak load decreased at this hole size, seeming as if the hole is too large. 6 of 8 tests or 75% failed at the knot and 2 of 8 tests or 25% failed at the anchor.

3.7 mm Hole Size

The anchor went into the hole with ease. The suture broke at the anchor four times during tests 4 through 7 and at the knot for the rest of the tests. The peak load continued to fall at this hole size. The hole is way too big for the anchor. 4 of 8 tests or 50% failed at the knot and 4 of 8 tests or 50% failed at the anchor.

Testing Results for Large Anchor Type B in Pig Bone

Diameter of hole (mm)	Number of tests performed	Average pull strength in pounds	Standard deviation in pounds
3.2	5	32.08	6.54
3.3	5	38.10	2.40
3.4	5	36.46	2.07
3.5	5	27.00	5.93

Overview

From the results, The pull strength peaked at the hole size of 3.3 mm and then began to decline. The hole size of 3.5 mm was to big for the anchor since three of the 5 anchors failed by anchor pullout during testing. The 3.5 mm hole size provided a stopping point for the pig bone testing. In this summary, *discoloration* means that the suture changed color in an area where it was pinched. *Fray* means that the some of the strands in the suture actually broke during injection - caused by pinching.

3.2mm hole size

For the 3.2 mm hole size, five anchors were used. The anchor was semi-hard to insert. The suture broke at the knot 4 out of 5 tests or 80% and failed by anchor pullout 1 out of 5 tests or 20%, during test 4. This is the smallest hole size that will be used for the bone testing model.

3.3 mm hole size

The hole seemed a little tight to moderate for the suture and the anchor to enter at the same time. It was semi-hard to inject the anchor into the hole for each test. The suture broke at the knot 3 out of 5 tests or 60% and 2 out of 5 tests or 40% at the anchor. There were no anchor failures by pullout. The 3.3 mm hole size obtained the highest peak load at 38.10 lbs.

3.4 mm Hole Size

The 3.4 mm hole size is the hole presently being used by surgeons. The hole seemed a little tight to moderate for the suture and the anchor to enter at the same time. For the most part, it was semi-hard to inject the anchor into the hole for each test. The suture broke at the anchor only once. There were no anchor failures. The peak load started to decline at this point. 4 of 5 tests or 80% failed at the knot and 1 of 5 tests or 20% failed at the anchor.

3.5 mm Hole Size

After insertion, two anchors pulled out upon toggle. Two new holes were drilled and two new anchors were used. 3 out of 5 tests or 60% failed with the anchor pulling out. Only 2 out of 5 tests or 40% failed at the knot and were successful with very low peak load results amongst them. The 3.5 mm hole size is to large for the suture anchor and is the last hole size used for this testing.

Summary of ANOVA Results

Anchor type	Dependent variable	Independent variables	Model	Results
Small A	pull strength	hole size	acrylic plate	(P = 94.4%) insignificant
Small B	pull strength	hole size	acrylic plate	(P = 84.1%) insignificant
Small B	pull strength	hole size	pig bone	(P = 8.78%) insignificant
Large A	pull strength	hole size	acrylic plate	(P = 83.3%) insignificant
Large B	pull strength	hole size	acrylic plate	(P = 33.8%) insignificant
*Large B	pull strength	hole size	pig bone	(P = 99.21%) significant